

Supplementary Material 1 TISU trial Paperwork

Recruitment

1. TISU log book
2. PIL
3. Consent form
4. Baseline questionnaire
5. GP letter

Follow-up questionnaires, letters and emails

1. Pre-treatment
2. 1 week post treatment
3. 1 week letter
4. 1 week email
5. 1 week letter reminder
6. 1 week email reminder
7. 8 week post randomisation
8. 8 week letter
9. 8 week email
10. 8 week letter reminder
11. 8 week email reminder
12. 6 month post randomisation
13. 6 month letter
14. 6 month email
15. 6 month letter reminder
16. 6 month email reminder

CRFs

1. Baseline
2. Treatment
3. Second treatment
4. 8 week
5. 6 month
6. Supplementary
7. Ineligible/declined form
8. SAE form
9. Change of status form

Study Centre No

TISU Log Book *(for use and retention my local hospital sites only)*

| Hospital Number | Date identified for study | Name | Date of Birth | PIL given Y/N | Eligible Y/N* | Consent Y/N* |
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* If No, complete ineligible/declined form



PATIENT INFORMATION LEAFLET

INVITATION TO TAKE PART

We would like to invite you to take part in a research study related to the treatment of your ureteric stone. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Talk to others about the study if you wish. Please feel free to ask questions if the information is not clear or if you would like more information.

BACKGROUND TO THE CONDITION

Ureteric stones are very common; 2-3% of the general population (1.8 million in the UK) have suffered from this condition. Ureteric stones have an impact on people's quality of life due to the severe pain which often requires pain killing medicines, and may require admission to hospital, time off work and interference with social activities.

Ureteric stones can pass in their own time and some patients will only require initial treatment with pain killers and, if appropriate, anti-sickness medication and drugs which relax the muscle fibres of the ureter. This can help the stone to come out. In some cases the treatments described above do not work or patients are not suitable for such care and further routine intervention (stone removal) is required.

There are a number of ways to get rid of ureteric stones. Two methods used to remove stones are:

- Extracorporeal Shockwave Lithotripsy (ESWL), which is a shockwave treatment applied from the outside of the body, and
- Ureteroscopic stone treatment, a telescopic procedure to remove the stone.

WHAT IS THE PURPOSE OF THE STUDY?

Urinary stone disease is very common and painful and the aim of treatment is to reduce pain and clear the ureteric stone. Both procedures are used in the NHS to remove stones but we do not know which treatment is better. In the TISU study we aim to find out which procedure is best. TISU aims to recruit 1000 participants. The study will generate high quality data that will be used to help determine the best treatment of patients with ureteric stones in the future.

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been chosen because you have been diagnosed with a ureteric stone in your ureter (the tube which drains the urine from the kidney to the bladder). Your doctor has decided that it is necessary to perform a routine procedure that will help remove the stone from your ureter.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not to take part. Please take as much time as you feel you need to make this decision. You can read this information sheet as many times as you wish and ask your doctor and/or research nurse as many questions as you need.

Whether or not you decide to take part in TISU, you will still receive care for your ureteric stone.

If you decide to take part we will ask you to sign a consent form confirming your agreement. However, even after you have signed this form, you are still free to withdraw at any time and without giving a reason. A decision to withdraw from the study will not affect the standard of care you receive.

WHAT WILL HAPPEN IF I TAKE PART?

Patients who agree to take part in TISU will be randomly allocated to either ESWL or ureteroscopy. The particular treatment given to each person in the study will be decided by a computer system (see the table below for further information about the two treatments). If you decide to take part this means that neither you nor your doctors can decide which treatment you will receive. There is an equal chance you will be placed into either treatment group.

| Group name | Procedure |
|--|--|
| ESWL (Extracorporeal Shockwave Lithotripsy) | <ul style="list-style-type: none">• A machine will send shock waves of energy through your skin to the stone to break it into smaller pieces so it can be passed in your urine.• Done as an out-patient appointment• Procedure may require pain medication and treatment normally lasts between 30 and 60 minutes.• A second treatment may be required within 6-8 weeks. |
| Ureteroscopy | <ul style="list-style-type: none">• Involves passing a long, thin telescope called a ureteroscope, through your urethra (tube that carries urine from the bladder to the outside of the body) and into your bladder. It is then passed up into your ureter to where the stone is stuck. The surgeon may either try gently to remove the stone using another instrument, or they may use laser energy to break the stone up into small pieces so that it can be passed naturally in your urine.• Day case procedure (but may require hospital admission)• Likely to require general anaesthetic |

Waiting times for treatment will reflect current care in the NHS and we expect the procedure will be conducted within approximately eight weeks of you agreeing to take part. Individual patient needs will be taken into consideration.

To collect the information we need, everyone in the study will be followed up in exactly the same way for a period of six months after you join the study. You will be asked to answer questions about your general health, pain and use of pain killers when you join the study, directly before your procedure and again one week after the procedure. At approximately eight weeks and six months after you join the study we will ask you to complete another

questionnaire. The questionnaires will ask you to detail the symptoms you experience due to your ureteric stone, pain, use of pain killers, additional treatment received and how your day to day life has been affected. We will send you up to two reminders and will aim to contact you by post, email and/or telephone, taking into account which communication method is best for yourself.

At 6 months you will receive a token of appreciation for your time spent on completing the TISU questionnaires. The voucher will be sent with your 6 month questionnaire.

The study nurse or doctor involved in the study will also collect information from your NHS records during the six months after you join the study.

After your treatment for your ureteric stone you will be asked to come back to an outpatient clinic at your hospital to check how you are getting on. If your symptoms are still not adequately controlled you may receive further treatment in the same way people with ureteric stones are usually treated. All the clinical care that you receive on the study will be the same as the standard care that is usually given.

Data for all participants in the study, including those who withdraw, will be kept securely for a minimum of 10 years.

WHAT WILL HAPPEN NEXT?

If you are happy to take part in the TISU study you will be asked a series of questions to make sure that your particular circumstances make you suitable for inclusion in the study. If you are suitable, you will be asked to sign a consent form and complete the first questionnaire. Your details will be entered into a computer system and you will be randomly allocated to receive one of the two treatment procedures. The doctors and nurses treating you will not be involved in your procedure allocation and have no control over what group you are put in. Both procedures are suitable for the treatment of your ureteric stone.

WHAT ARE THE POSSIBLE BENEFITS TO ME OF TAKING PART?

You will receive the same health care from your doctors whether or not you choose to participate in the study or not. You may not benefit personally from taking part in this study.

By taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with ureteric stones. The results of the study will help plan effective services offered by the NHS.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no anticipated risks or disadvantages to participating in TISU. Whichever group you are allocated to, your procedure will be performed by a competent and trained urologist. There are risks associated with all procedures and anaesthetics. Steps are always taken to ensure that these risks are minimised. As part of routine care, you will be well informed of potential risks.

The reported side effects of ESWL include:-

Common (greater than 1 in 10)

Bleeding on passing urine for a short period of time after the procedure, pain in the kidneys, urinary tract infection (10 %), bruising of abdomen/loin skin.

Occasional (between 1 in 10 and 1 in 50) stone fragments stuck between kidney and bladder that require surgery to remove them.

Uncommon (less than 1 in 50)

Infection requiring intravenous antibiotics (less than 1%), kidney damage or infection requiring treatment, recurrence of stones (less than 1%).

Reported Ureteroscopy side effects include:-**Common (greater than 1 in 10)**

Mild burning or bleeding on passing urine for short period after procedure, temporary insertion of bladder catheter, insertion of stent (stent may cause pain) and further procedure to remove it.

Occasional (between 1 in 10 and 1 in 50)

Inability to retrieve stone or movement of stone into kidney, kidney damage or infection requiring treatment, failure to pass the telescope, recurrence of stones.

Uncommon (less than 1 in 50)

Damage to ureter with need for operation, very rarely scarring of ureter requiring further procedures.

You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Your doctor will continue your care and treatment as standard. If the study is stopped earlier than expected for any reason, you will be told and your continuing care will be arranged.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

If new relevant information or treatments become available during the study the TISU Study Office staff will get in touch with you to let you know about the choices available to you

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. All the procedures and techniques are already being used in the NHS to treat ureteric stones. Your participation in TISU is therefore only to help us evaluate these procedures and should not involve any additional risk to you.

However, if you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of the study, University of Aberdeen and NHS Grampian. Contact details for both research sponsors are available through the research team.

As a patient of the NHS if you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

If you have a concern about any aspect of this study you should ask to speak to the researchers who will answer your questions (contact details of your local study nurse and the TISU Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or Private Institution). Contact details can be obtained from your local hospital. In addition to this, you may contact the chairman of the TISU Trial Steering Committee.

If you become unable or unwilling to continue in TISU we would withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information that is collected about you during the course of the study will be kept strictly confidential and will be held securely in accordance with the Data Protection Act.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for instance, to send you the questionnaires.

If you participate in the study we will tell your GP you are taking part, but only with your permission. We will also ask your GP to contact us if you visit them with any problems that may relate to your ureteric stone.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can withdraw from the study at any time, but you will need to continue attending appointments with your consultant and/or GP in order to have your ureteric stones monitored as part of your standard care.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with ureteric stones. The results of this study will also be published in scientific journals and presented at scientific meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study has been designed by UK urological medical doctors and researchers. Patients will be recruited at different hospitals throughout the UK. The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. It is being co-ordinated by The Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered clinical trials unit, at the University of Aberdeen.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed by a NHS Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans, in accordance with the Clinical Trials Regulations. In this case, the reviewing Committee was the North of Scotland Research Ethics Committee who have raised no objections.

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny if requested by monitors from the sponsors, the Research and Development Department of your local hospital and the Regulatory Authorities whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

Other researchers may wish to access data from this study in the future (this will not include names, addresses or dates of birth, and it is not possible to identify participants from the data). If this is the case, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

THANK YOU

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the TISU study. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

Study Office contact details:

***TISU Study Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen AB25 2ZD
Telephone: +44 (0)1224 438189
Email: tisu@abdn.ac.uk
Website:
<http://www.charttrials.abdn.ac.uk/tisu>***

Local contact details:

<<Insert contact details of local PI and/or Research Nurse>>

TRIAL CONSENT FORM

Participant Study No

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Please initial
ALL boxes



By signing this form and initialing each box:

1) I agree that I have

- been given the Information Sheet about the study (Version....., date.....)
- had the opportunity to discuss the study and all my questions have received satisfactory answers
- understood the purpose of the study and I know what my involvement will be

| |
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| |

2) I understand that

- my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected
- information relevant to the TISU Trial may be collected from my hospital and NHS records, including Office of National Statistics (ONS) and NHS central registers
- relevant sections of my medical notes and data collected during the study may be looked at by individuals directly involved in the trial, from regulatory authorities or from the NHS Health Boards or Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- my personal contact details will be kept confidentially and securely by the study office in Aberdeen. I agree that the study co-ordinators can use my contact details to send me relevant study information and questionnaires and to contact me by phone, post or email.
- my family doctor (GP) will be told that I am taking part in this trial.

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I agree to take part in the study

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Your signature (participant)

Your name in block capitals

Date

For office use only

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature

Name in block capitals

Date

The TISU Trial Office, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel 01224 438189; Fax 01224 438165; tisu@abdn.ac.uk

Copies: 1 for trial office in Aberdeen (top copy); 1 for patient; 1 for site file, 1 to be filed with hospital notes.

Participant Study Number

| | | | | |
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Therapeutic Interventions for Stones of the Ureter

BASELINE QUESTIONNAIRE

CONFIDENTIAL

This study is funded by the NHS National Institute for Health
Research Health Technology Assessment Programme

The following questionnaire is broken down into three sections (Section A - Section C). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a cross (X) in the appropriate box, and other sections ask you to circle your answer.

Please read the questions carefully and answer each one as accurately as you can.

The sections covered in this questionnaire are as follows:

Contact Information

Section A: Your Pain

Section B: Describing Your Own Health Today (EQ-5D)

Section C: Your General Health (SF-12©)

Section D: Cambridge Ureteric Stone Patient Reported Outcome (CUSP)

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

Your answers will be treated with complete confidentiality.

Thank you for your time in completing this questionnaire.

| | | | | |
|--|--|--|--|--|
| | | | | |
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Study Number

Please start here

Date questionnaire filled in:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

CONTACT INFORMATION

In order that we can keep in touch with you by the methods that best suit you can you:

Please give us your email address

Please give us your mobile telephone number

| | | | | | | | | | | | |
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How would you prefer to complete the future study questionnaires?

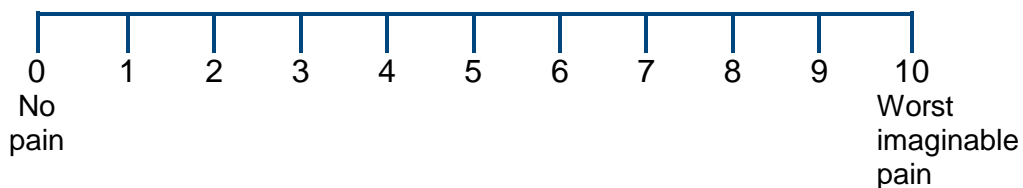
A paper copy sent by post An email sent to complete it online

SECTION A: YOUR PAIN

A1. Please rate the level of pain that you are experiencing TODAY.

The following line represents pain of increasing intensity from 'no pain' to 'worst imaginable pain'. The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain).

Please circle the most appropriate number that describes your pain today.



A2. During the last 7 days have you had pain related to your ureteric stone? Yes No

How many days, out of the last 7, have you taken any pain relief medication?

| | | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

SECTION B: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

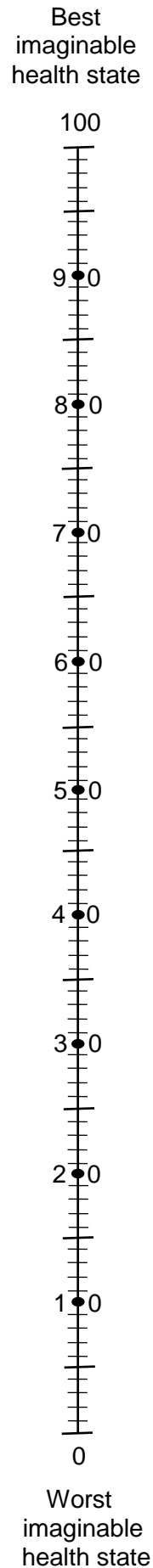
| | | |
|---|--|--------------------------|
| B1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| B2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| B3. Usual Activities <i>(e.g. work, study, housework, family or leisure activities)</i> | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| B4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| B5. Anxiety/Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

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To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**YOUR OWN
HEALTH STATE
TODAY**



SECTION C: YOUR HEALTH AND WELL BEING (SF-12)

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

| Excellent | Very good | Good | Fair | Poor |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|--|--------------------------|--------------------------|--------------------------|
| a) <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) <u>Climbing several flights of stairs</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Were limited in the <u>kind</u> of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did work or other activities <u>less carefully than usual</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Have you felt calm and peaceful?</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you felt downhearted and low? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust.(IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

SECTION D: CAMBRIDGE URETERIC STONE REPORTED OUTCOME MEASURE

We would like to understand the impact that your stone has had on your wellbeing and health. We would be grateful if you would complete the following questions that have been designed specifically for ureteric stone patients.

Please respond to each question or statement by marking ONE box per row

Pain¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| How much did pain interfere with your day to day activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with work around the home? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your ability to participate in social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with the things you usually do for fun? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your household chores? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your family life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Fatigue¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I feel fatigued | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble starting things because I am tired | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How run-down did you feel in general? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How fatigued were you on average? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much were you bothered by fatigue? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Work and daily activities¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have trouble doing all of my regular leisure activities with others | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of the family activities that I want to do | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of my usual work (include work at home) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Sleep Disturbance¹

| During the past 7 days | Very poor | Poor | Fairt | Good | Very Good |
|---------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| My sleep quality was | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| | Not at all | A little bit | Somewhat | Quite a bit | Very much |
| My sleep was refreshing | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had a problem with my sleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had difficulty falling asleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Anxiety¹

| During the past 7 days | Never | Rarely | Sometimes | Often | Always |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I felt fearful | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I found it hard to focus on anything other than my anxiety | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| My worries overwhelmed me | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Urinary Symptoms²

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have had blood in my urine | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I urinate more frequently than usual | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| It burns when I urinate | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

**Once you have completed the form,
please return it in the pre-paid envelope provided or to the following address:**

**The TISU Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 438189
Fax: 01224 438165
Email: tisu@abdn.ac.uk
<http://www.chartrials.abdn.ac.uk/tisu>**

TISU GP letter and information sheet – printed on TISU letter headed paper

Dr <<GP Name>>
<<GP Address 1>>
<<GP Address 2>>
<< GP Address 3>>
<< GP Address 4>>
<< GP Postcode>>

Date

Dear Dr <<Surname>>

Patient name: <<Name>>

Date of birth: <<dob>>

Patient address: <<address>>

Title of study: TISU (Therapeutic Interventions for Stones of the Ureter)

Your patient has consented to take part in this study which is a multi centre trial funded by the NIHR Health Technology Assessment Programme. The aim of the trial is to provide robust data to guide the treatment of patients with ureteric stones needing intervention. Your patient has been given written information about the trial, including contact details at the hospital and of the central office in Aberdeen.

Your patient has been randomised to either extracorporeal shockwave lithotripsy (ESWL) or ureteroscopic treatment. Participants will be sent postal questionnaires from the central co-ordinating office in Aberdeen to complete at approximately one week after treatment and eight weeks and six months after randomisation.

We should not normally need to obtain any information from you. However, we would be grateful if you could contact telephone number 01224 xxxxxx or email tisu@abdn.ac.uk if your patient changes address, is too ill to continue taking part, has an adverse event following their ureter stone treatment or dies.

If you would like to discuss any aspect of our trial, or require any further details, please do not hesitate to contact the TISU Study Office.

A more detailed description of the study background is on the back of this letter.

Yours sincerely,

Trial Manager

Prof Sam McClinton, Chief Investigator

GP INFORMATION SHEET

Title of project

TISU (Therapeutic Interventions for Stones of the Ureter) is a multicentre randomised controlled trial of extracorporeal shockwave lithotripsy, as first treatment option, compared with direct progression to ureteroscopic treatment, for ureteric stones.

Background

Urinary stone disease is very common with an estimated prevalence among the general population of 2–3% (1.8 million people in the UK) with males forming stones three times as often as females. Urinary stones often recur and the lifetime recurrence rate is approximately 50%. The interval between recurrences is variable, with approximately 10% within one year, 35% within five years, and 50% within 10 years. Urinary tract stones, and ureteric stones, in particular, are associated with severe pain as they pass through the urinary tract and can have a significant impact on patients' quality of life due to the detrimental effect on their ability to work and the need for hospitalisation.

Most ureteric stones can be expected to pass spontaneously with supportive care (painkillers and fluids) possibly aided by drugs such as alpha-blockers or calcium channel blockers (conservative management). However, between a fifth and a third of cases require an active intervention (stone removal) because of failure to pass the stone, continuing pain, infection or obstruction to urine drainage. The two standard active intervention options are extracorporeal shockwave lithotripsy (ESWL) and ureteroscopy. Whilst both ESWL and ureteroscopy appear to be effective in terms of stone clearance they differ in terms of invasiveness, anaesthetic requirement, treatment setting, the number of procedures required to clear the stone, complications, patient reported outcomes (such as severity and duration of pain after intervention, time off work and bothersome urinary symptoms), and cost. There is uncertainty around which is the most clinically effective in terms of stone clearance and the true cost to the NHS and to society (in terms of impact on patient reported health and economic burden). The TISU trial will inform patients, clinicians and policy makers on the optimal choice of treatment for symptomatic ureteric stones.

Brief outline of the study

The research question that is being addressed is whether in adults with ureteric stones judged to require active intervention extracorporeal shockwave lithotripsy (ESWL) is more effective and cost-effective compared to ureteroscopic treatment as the initial management option. The hypothesis being tested is that the outcome in patients receiving ESWL as their first treatment option is not inferior to the outcome in patients receiving ureteroscopic treatment.

Ethical and regulatory approvals have been obtained for this trial and written consent has been obtained from participants. Participants may be reviewed in outpatients as required and as per normal clinical practice. The primary clinical outcome of the trial is the clinical resolution of the ureteric stone episode defined as "no further intervention required to facilitate stone clearance" up to six months from randomisation. To reflect the multidimensional nature of the possible effects the intervention may have, there is also a primary health economic outcome of incremental cost per quality adjusted life years (QALYs) gained at six months from randomisation.

Participant Study Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|



Therapeutic Interventions for Stones of the Ureter

PRE-TREATMENT QUESTIONNAIRE

CONFIDENTIAL

This study is funded by the NHS National Institute for Health
Research Health Technology Assessment Programme

The following questionnaire is broken down into two sections (Section A - Section C). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a cross (X) in the appropriate box, and other sections ask you to circle your answer.

Please read the questions carefully and answer each one as accurately as you can.

The sections covered in this questionnaire are as follows:

Section A: Your Pain

Section B: Describing Your Own Health Today (EQ-5D)

Section C Cambridge Ureteric Stone Patient Reported Outcome (CUSP)

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

Your answers will be treated with complete confidentiality.

Thank you for your time in completing this questionnaire.

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

Please start here

Date questionnaire filled in:

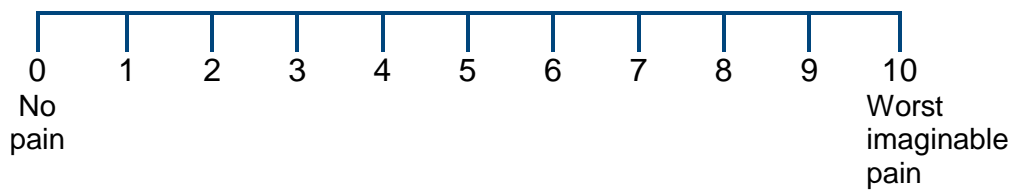
| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | / | | | / | | | | |
| D | D | | M | M | | Y | Y | Y | Y |

SECTION A: YOUR PAIN

A1. Please rate the level of pain that you are experiencing TODAY.

The following line represents pain of increasing intensity from 'no pain' to 'worst imaginable pain'. The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain).

Please circle the most appropriate number that describes your pain today.



A2. During the last 7 days have you had pain related to your ureteric stone? Yes No

How many days, out of the last 7, have you taken any pain relief medication?

| | | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

SECTION B: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

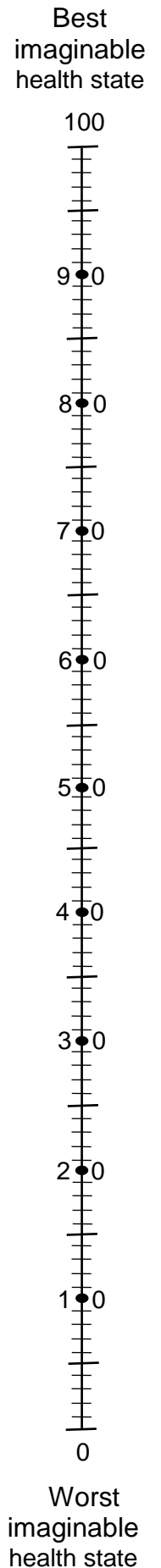
By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

| | | |
|---|--|--------------------------|
| B1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| B2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| B3. Usual Activities <i>(e.g. work, study, housework, family or leisure activities)</i> | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| B4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| B5. Anxiety/ Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**YOUR OWN
HEALTH STATE
TODAY**



SECTION C: CAMBRIDGE URETERIC STONE REPORTED OUTCOME MEASURE

We would like to understand the impact that your stone has had on your wellbeing and health. We would be grateful if you would complete the following questions that have been designed specifically for ureteric stone patients.

Please respond to each question or statement by marking ONE box per row

Pain¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| How much did pain interfere with your day to day activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with work around the home? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your ability to participate in social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with the things you usually do for fun? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your household chores? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your family life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Fatigue¹

During the past 7 days

I feel fatigued

Not at all

A little bit

Somewhat

Quite a bit

Very much

₁₂₃₄₅

I have trouble starting things because I am tired

₁₂₃₄₅

How run-down did you feel in general?

₁₂₃₄₅

How fatigued were you on average?

₁₂₃₄₅

How much were you bothered by fatigue?

₁₂₃₄₅

Subtotal:

Work and daily activities¹

During the past 7 days

I have trouble doing all of my regular leisure activities with others

Not at all

A little bit

Somewhat

Quite a bit

Very much

₁₂₃₄₅

I have trouble doing all of the family activities that I want to do

₁₂₃₄₅

I have trouble doing all of my usual work (include work at home)

₁₂₃₄₅

Subtotal:

Sleep Disturbance¹

During the past 7 days

My sleep quality was

Very poor

Poor

Fairt

Good

Very Good

₁₂₃₄₅

My sleep was refreshing

Not at all

A little bit

Somewhat

Quite a bit

Very much

₁₂₃₄₅

I had a problem with my sleep

₁₂₃₄₅

I had difficulty falling asleep

₁₂₃₄₅

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Anxiety¹

| During the past 7 days | Never | Rarely | Sometimes | Often | Always |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I felt fearful | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I found it hard to focus on anything other than my anxiety | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| My worries overwhelmed me | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Urinary Symptoms²

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have had blood in my urine | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I urinate more frequently than usual | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| It burns when I urinate | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

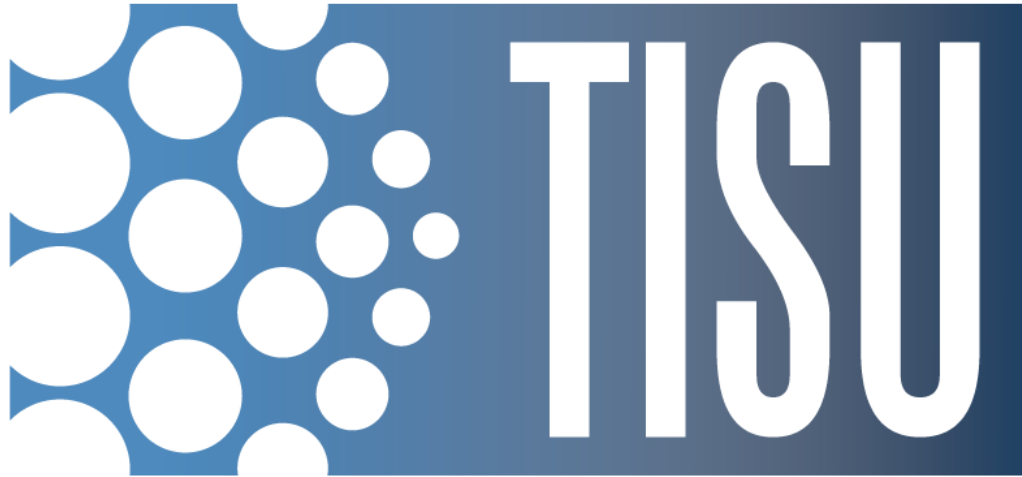
THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

**Once you have completed the form,
please return it in the pre-paid envelope provided or to the following address:**

**The TISU Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 438189
Fax: 01224 438165
Email: tisu@abdn.ac.uk
<http://www.charttrials.abdn.ac.uk/tisu>**

Participant Study Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|



Therapeutic Interventions for Stones of the Ureter

1 WEEK QUESTIONNAIRE

1 WEEK QUESTIONNAIRE

CONFIDENTIAL

This study is funded by the NHS National Institute for Health
Research Health Technology Assessment Programme

The following questionnaire is broken down into two sections (Section A - Section C). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a cross **(X)** in the appropriate box, and other sections ask you to circle your answer.

Please read the questions carefully and answer each one as accurately as you can.

The sections covered in this questionnaire are as follows:

Section A: Your Pain

Section B: Describing Your Own Health Today (EQ-5D)

Section C: Cambridge Ureteric Stone Patient Reported Outcome (CUSP)

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

Your answers will be treated with complete confidentiality.

Thank you for your time in completing this questionnaire.

Please start here

Date questionnaire filled in:

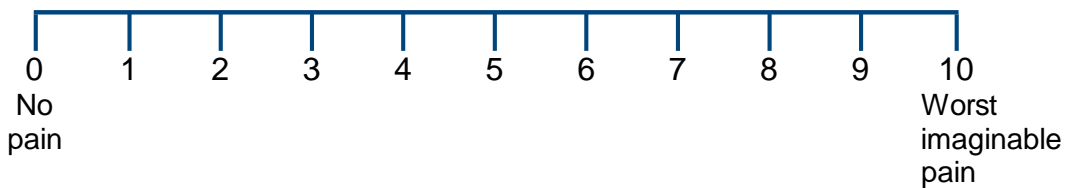
| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

SECTION A: YOUR PAIN

A1. Please rate the level of pain that you are experiencing TODAY.

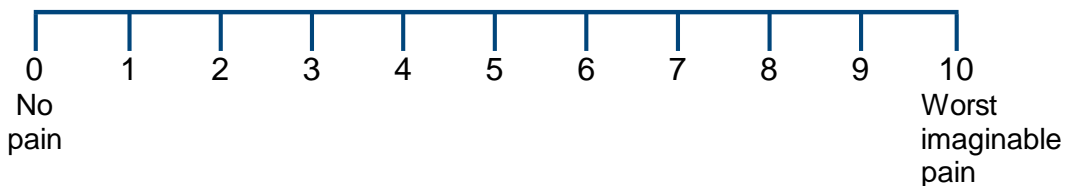
The following line represents pain of increasing intensity from 'no pain' to 'worst imaginable pain'. The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain).

Please circle the most appropriate number that describes your pain today.



A2. Please rate the WORST level of pain that you have experienced SINCE YOUR TRIAL TREATMENT.

The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a circle around the most appropriate number that describes your worst pain since your treatment.



A3. During the last 7 days have you had pain related to your ureteric stone? Yes No

How many days, out of the last 7, have you taken any pain relief medication?

| | | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

SECTION B: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

| | | |
|--|--|--------------------------|
| B1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| B2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| B3. Usual Activities (e.g. work, study, housework, family or leisure activities) | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| B4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| B5. Anxiety/ Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**YOUR OWN
HEALTH STATE
TODAY**

Best
imaginable
health state

100

90

80

70

60

50

40

30

20

10

0

Worst
imaginable
health state

SECTION C: CAMBRIDGE URETERIC STONE REPORTED OUTCOME MEASURE

We would like to understand the impact that your stone has had on your wellbeing and health. We would be grateful if you would complete the following questions that have been designed specifically for ureteric stone patients.

Please respond to each question or statement by marking ONE box per row

Pain¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| How much did pain interfere with your day to day activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with work around the home? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your ability to participate in social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with the things you usually do for fun? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your household chores? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your family life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| Subtotal: | | | | | |

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Fatigue¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I feel fatigued | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble starting things because I am tired | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How run-down did you feel in general? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How fatigued were you on average? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much were you bothered by fatigue? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Work and daily activities¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have trouble doing all of my regular leisure activities with others | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of the family activities that I want to do | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of my usual work (include work at home) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Sleep Disturbance¹

| During the past 7 days | Very poor | Poor | Fairt | Good | Very Good |
|---------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| My sleep quality was | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| | Not at all | A little bit | Somewhat | Quite a bit | Very much |
| My sleep was refreshing | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had a problem with my sleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had difficulty falling asleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Anxiety¹

| During the past 7 days | Never | Rarely | Sometimes | Often | Always |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I felt fearful | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I found it hard to focus on anything other than my anxiety | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| My worries overwhelmed me | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Urinary Symptoms²

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have had blood in my urine | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I urinate more frequently than usual | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| It burns when I urinate | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

**Once you have completed the form,
please return it in the pre-paid envelope provided or to the following address:**

**The TISU Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 438189
Fax: 01224 554580
Email: tisu@abdn.ac.uk
<http://www.charttrials.abdn.ac.uk/tisu>**

<<TISU HEADED PAPER>>
1 week post treatment letter

<< Date >>

<<Participant Title & Name>>

TISU STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Participant Title & Name>>

The TISU STUDY – 1 week post-treatment questionnaire

You recently underwent treatment for your ureteric stone. As you have kindly agreed to take part in the TISU study we are keen to find out how you have been getting on.

The questionnaire will have been given to you by your doctor or nurse at the hospital and you will also have been given a stamped addressed envelope to send this form back to us. We would also like to give you the option, if you would prefer, to complete the questionnaire online via the TISU website.

You can access the TISU website at the following address: www.chartrials.abdn.ac.uk/tisu.

Click on the link 'participant login'. Your login to access the TISU website is shown below:
Login ID: <<loginID>>

Please feel free to complete the questionnaire by whichever means is easier for you.

Although some of the questions may not seem relevant, we would like you to complete the questionnaire as fully as you can. Your experience is relevant for the study and the information you provide is very important.

If you have any problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, you can contact the TISU study office on 01224 438189 or email tisu@abdn.ac.uk.

We would like to thank you very much for taking part in the TISU study and for completing the questionnaire as your views and information about your recovery are very important to improving the management of patients that have ureteric stones in the future.

With our very best wishes and thanks for your help.

Yours sincerely

Sarah Cameron
Trial Manager

TISU – text to be sent to participants who request email contact to complete 1 week questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY – 1 week post-treatment questionnaire

You recently underwent treatment for your ureteric stone. As you have kindly agreed to take part in the TISU study we are keen to find out how you have been getting on.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the TISU study questionnaire online. Your password is **XXXXXXXXXX**

Although some of the questions may not seem relevant, we would like you to complete the questionnaire as fully as you can. Your experience is relevant for the study and the information you provide is very important.

If you have any problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, you can contact the TISU study office on 01224 43xxxx or email tisu@abdn.ac.uk.

We would like to thank you very much for taking part in the TISU study and for completing the questionnaire as your views and information about your recovery are very important to improving the management of patients that have ureteric stones in the future.

With our very best wishes and thanks for your help.

Xxxxxxx xxxxxxx
Trial Manager

<<TISU HEADED PAPER>>
1 week post treatment reminder

<< Date >>

<<Participant Title & Name>>

TISU STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Participant Title & Name>>

The TISU STUDY

Thank you very much for recently agreeing to take part in the TISU Study. We recently sent you the first of three follow-up questionnaires, but unfortunately we have not yet received your answers.

We are keen to find out how you have been getting on since you had your stone treatment. You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer the enclosed questionnaire and return it in the pre-paid envelope (no need for a stamp). If your reply is already in the post, thank you for your help and our apologies for this reminder.

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 438189 or email e-mail: tisu@abdn.ac.uk.

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager

Sarah Cameron

TISU – reminder text to be sent to participants who request email contact to complete 1 week questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY

Thank you very much for recently agreeing to take part in the TISU Study. We recently emailed you the link to complete the first of three follow-up questionnaires but unfortunately we have not yet received your answers.

We are keen to find out how you have been getting on since you agreed to take part in the study. You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer questionnaire on the link below.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the questionnaire online. Your password is **XXXXXXXXXX**

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 XXXXXX or email e-mail: tisu@abdn.ac.uk.

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager

Participant Study Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|



Therapeutic Interventions for Stones of the Ureter

8 WEEK QUESTIONNAIRE POST-RANDOMISATION

CONFIDENTIAL

This study is funded by the NHS National Institute for Health
Research Health Technology Assessment Programme

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

The following questionnaire is broken down into four sections (Section A - Section D). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a cross (X) in the appropriate box, and other sections ask you to circle your answer.

Please read the questions carefully and answer each one as accurately as you can.

The sections covered in this questionnaire are as follows:

Section A: Your Level of Pain

Section B: Your Hospital Experience

Section C: Describing Your Own Health Today (EQ-5D)

Section D: Your General Health (SF-12©)

Section E Cambridge Ureteric Stone Patient Reported Outcome (CUSP)

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

Your answers will be treated with complete confidentiality.

Thank you for your time in completing this questionnaire.

Please start here

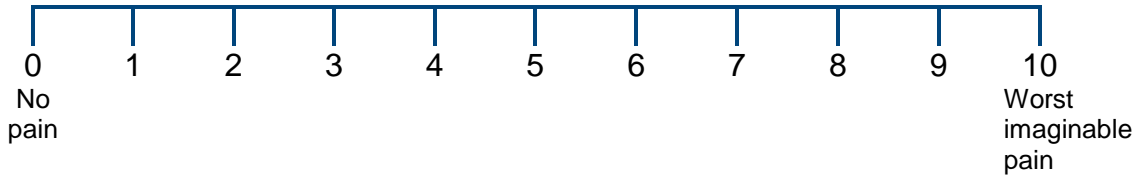
Date questionnaire filled in:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

SECTION A: YOUR LEVEL OF PAIN

A1. Please rate the level of pain, related to your ureteric stone, that you are experiencing TODAY.

The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a circle around the most appropriate number that describes your pain today.



A2. In the past SEVEN DAYS have you had pain related to your ureteric stone?

Yes

No

How many days, out of the last 7, have you taken any pain relief medication?

0 1 2 3 4 5 6 7

SECTION B: YOUR HOSPITAL EXPERIENCE

B1. If you had a friend with a ureteric stone would you recommend the same treatment as you have had to him/her?

Yes

No

B2. Please rate how important the following items were for you in the period after your treatment : (1 = least important; 6 = most important)

| | |
|---|--------------------------|
| Duration of hospital stay | <input type="checkbox"/> |
| Need for further treatment | <input type="checkbox"/> |
| No complications | <input type="checkbox"/> |
| Pain after treatment | <input type="checkbox"/> |
| Delay in resuming normal daily activities | <input type="checkbox"/> |
| Time off work | <input type="checkbox"/> |

Study Number

SECTION C: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

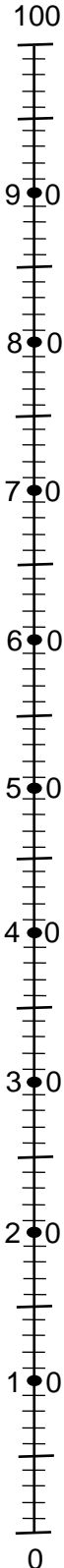
| | | |
|--|--|--------------------------|
| C1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| C2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| C3. Usual Activities (e.g. work, study, housework, family or leisure activities) | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| C4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| C5. Anxiety/ Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**YOUR OWN
HEALTH STATE
TODAY**

Best
imaginable
health state



Worst
imaginable
health state

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

SECTION D: YOUR HEALTH AND WELL BEING (SF-12)

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

| Excellent | Very good | Good | Fair | Poor |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|--|--------------------------|--------------------------|--------------------------|
| a) <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) <u>Climbing several flights of stairs</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Were limited in the <u>kind</u> of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did work or other activities <u>less carefully than usual</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Have you felt calm and peaceful?</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you felt downhearted and low? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust.(IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

SECTION D: CAMBRIDGE URETERIC STONE REPORTED OUTCOME MEASURE



We would like to understand the impact that your stone has had on your wellbeing and health. We would be grateful if you would complete the following questions that have been designed specifically for ureteric stone patients.

Please respond to each question or statement by marking ONE box per row

Pain¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| How much did pain interfere with your day to day activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with work around the home? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your ability to participate in social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with the things you usually do for fun? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your enjoyment of social activities? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your household chores? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much did pain interfere with your family life? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

Fatigue¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I feel fatigued | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble starting things because I am tired | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How run-down did you feel in general? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How fatigued were you on average? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| How much were you bothered by fatigue? | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Work and daily activities¹

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have trouble doing all of my regular leisure activities with others | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of the family activities that I want to do | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I have trouble doing all of my usual work (include work at home) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Sleep Disturbance¹

| During the past 7 days | Very poor | Poor | Fairt | Good | Very Good |
|---------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| My sleep quality was | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| | Not at all | A little bit | Somewhat | Quite a bit | Very much |
| My sleep was refreshing | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had a problem with my sleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I had difficulty falling asleep | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

Anxiety¹

| During the past 7 days | Never | Rarely | Sometimes | Often | Always |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I felt fearful | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I found it hard to focus on anything other than my anxiety | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| My worries overwhelmed me | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Urinary Symptoms²

| During the past 7 days | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|--------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| I have had blood in my urine | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| I urinate more frequently than usual | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| It burns when I urinate | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

Subtotal:

Reference

1. PROMIS Health Organisation and PROMIS Cooperative Group
2. FACIT measurement system and FACIT.org

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

**Once you have completed the form,
please return it in the pre-paid envelope provided or to the following address:**

**The TISU Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 438189
Fax: 01224 438165
Email: tisu@abdn.ac.uk
<http://www.chartrials.abdn.ac.uk/tisu>**

| | | | | |
|--|--|--|--|--|
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|--|--|--|--|--|

Study Number

<<TISU HEADED PAPER>>
8 week post randomisation letter

<< Date >>

<<Participant Title & Name>>

TISU STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Participant Title & Name>>

The TISU STUDY

It is now approximately eight weeks since you joined the TISU study - many thanks for taking part. We are keen to find out how you have been getting on since you joined the study so please find enclosed the second of the three follow-up questionnaires. Whether you are still waiting for your treatment to start or your treatment is now complete, your experience is relevant for the study and the information you provide is very important.

If you have just recently undergone your treatment for your ureteric stone, you may have recently completed/received a short questionnaire from the study. However we would still appreciate it if you could also complete this questionnaire. The questionnaire can be returned in the reply-paid envelope provided (no stamp is required). Please note that ALL the information you give will be treated with the strictest confidence.

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively please contact the TISU Study Office on 01224 xxxxxx or email -mail: tisu@abdn.ac.uk.

Thank you again for taking part in the TISU study. Your views and information about your recovery are very important to improving the management of patients that suffer from ureteric stones in the future.

With our very best wishes,

XXXXXXXXX
Trial Manager

Enclosures: Eight week TISU questionnaire
Reply-paid envelope

Version 1, 1 Dec 2012

TISU – text to be sent to participants who request email contact to complete 8 week questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY

It is now approximately eight weeks since you joined the TISU study - many thanks for taking part. We are keen to find out how you have been getting on since you joined the study. Please click on the link below to complete the second online questionnaire.

Whether you are still waiting for your treatment to start or your treatment is now complete, your experience is relevant for the study and the information you provide is very important. If you have just recently undergone your treatment for your ureteric stone, you may have recently completed a short questionnaire from the study. However we would still appreciate it if you could also complete this questionnaire. Please note that ALL the information you give will be treated with the strictest confidence.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the TISU study questionnaire online. Your password is **XXXXXXXXXX**

Although some of the questions may not seem relevant, we would like you to complete the questionnaire as fully as you can. Your experience is relevant for the study and the information you provide is very important.

If you have any problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, you can contact the TISU study office on 01224 43xxxx or email tisu@abdn.ac.uk.

We would like to thank you very much for taking part in the TISU study and for completing the questionnaire as your views and information about your recovery are very important to improving the management of patients that have ureteric stones in the future.

With our very best wishes,

XXXXXXXXXX
Trial Manager

<<TISU HEADED PAPER>>
8 week post randomisation reminder letter

<< Date >>

<<Participant Title & Name>>

TISU STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Participant Title & Name>>

The TISU STUDY

It is now over eight weeks since you kindly agree to take part in the TISU study. We sent you the second of three follow-up questionnaires a few weeks ago, but unfortunately we have not yet received your answers. We are keen to find out how you have been getting on since you agreed to take part in the study.

You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer the enclosed questionnaire and return it in the pre-paid envelope (no need for a stamp). If your reply is already in the post, thank you for your help and our apologies for this reminder.

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 XXXXXX or email e-mail: tisu@abdn.ac.uk

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager

TISU – reminder text to be sent to participants who request email contact to complete 8 week questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY

It is now over eight weeks since you kindly agree to take part in the TISU study. We sent you the link to complete second of three online follow-up questionnaires a few weeks ago, but unfortunately we have not yet received your answers.

We are keen to find out how you have been getting on since you agreed to take part in the study. You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer questionnaire on the link below.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the questionnaire online. Your password is **XXXXXXXXXX**

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 XXXXXX or email e-mail: tisu@abdn.ac.uk.

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager

Participant Study Number

| | | | | |
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Therapeutic Interventions for Stones of the Ureter

6 MONTH QUESTIONNAIRE POST-RANDOMISATION

CONFIDENTIAL

This study is funded by the NHS National Institute for Health
Research Health Technology Assessment Programme

The following questionnaire is broken down into three sections (Section A - Section C). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a cross (X) in the appropriate box, and other sections ask you to circle your answer.

Please read the questions carefully and answer each one as accurately as you can.

The sections covered in this questionnaire are as follows:

Section A: Health Service Use

Section B: Describing Your Own Health Today (EQ-5D)

Section C: Your General Health (SF-12©)

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

Your answers will be treated with complete confidentiality.

Thank you for your time in completing this questionnaire.

Please start here

Date questionnaire filled in:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

| | | | | |
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Study Number

SECTION A: HEALTH SERVICE USE

Please fill in all the questions by crossing the relevant box of the answer that applies to you or writing in the information requested.

A1. Have you needed any further treatment or surgery to treat your ureteric stone symptoms?

Yes No

A1a. If Yes, can you please tell us what treatment you had, the name of the hospital where you had the further treatment, approximately what date this was and how long you stayed in hospital?

| What treatment did you have? | Name of the hospital? | Date of treatment? | Length of time in hospital (days)? |
|------------------------------|-----------------------|--------------------|------------------------------------|
| | | | |
| | | | |

A2. Have you visited NHS hospital outpatients to see a doctor, in relation to your ureteric stone symptoms since you had your initial treatment?

Yes No

A2a. If Yes specify the number of times you have been seen:

times

A3. Have you seen your GP, in relation to your ureteric stone symptoms since you joined the TISU trial?

Yes No

A3a. If yes how many times did you see your GP?

times

A4. Have you seen a practice nurse in relation to your ureteric stone symptoms since you joined the TISU trial?

Yes No

A4a. If yes, how many times did you see the nurse?

times

A5. Were you prescribed any medicines by a doctor or nurse in relation to your ureteric stone symptoms since you joined the TISU trial?

Yes No

A6. Did you buy any medicines over the counter to treat your ureteric stone symptoms since you joined the TISU trial?

Yes No

A6a. If yes how much in total did you spend?

£

A7. Did you pay to see any private health care professional, in relation to your ureteric stone symptoms since you joined the TISU trial?

Yes No

A7a. If yes how much in total did you spend?

£

SECTION B: DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

By placing a cross in one box in each group below, please indicate which statements best describe your own health state today

| | | |
|--|--|--------------------------|
| B1. Mobility | I have no problems in walking about | <input type="checkbox"/> |
| | I have some problems in walking about | <input type="checkbox"/> |
| | I am confined to bed | <input type="checkbox"/> |
| B2. Self-care | I have no problems with self-care | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | <input type="checkbox"/> |
| | I am unable to wash or dress myself | <input type="checkbox"/> |
| B3. Usual Activities (e.g. work, study, housework, family or leisure activities) | I have no problems with performing my usual activities | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | <input type="checkbox"/> |
| | I am unable to perform my usual activities | <input type="checkbox"/> |
| B4. Pain/Discomfort | I have no pain or discomfort | <input type="checkbox"/> |
| | I have moderate pain or discomfort | <input type="checkbox"/> |
| | I have extreme pain or discomfort | <input type="checkbox"/> |
| B5. Anxiety/ Depression | I am not anxious or depressed | <input type="checkbox"/> |
| | I am moderately anxious or depressed | <input type="checkbox"/> |
| | I am extremely anxious or depressed | <input type="checkbox"/> |

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| | | | | |
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Study Number

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**YOUR OWN
HEALTH STATE
TODAY**

Best
imaginable
health state

100



90

80

70

60

50

40

30

20

10

0

Worst
imaginable
health state

SECTION C: YOUR HEALTH AND WELL BEING (SF-12)

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

| Excellent | Very good | Good | Fair | Poor |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|--|--------------------------|-----------------------------|------------------------------|
| a) <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) <u>Climbing several flights of stairs</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | |
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|--|--|--|--|--|

Study Number

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Were limited in the <u>kind</u> of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u> than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did work or other activities <u>less carefully than usual</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Have you felt calm and peaceful?</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you felt downhearted and low? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Study Number

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

**Once you have completed the form,
please return it in the pre-paid envelope provided or to the following address:**

**The TISU Trial Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 438189
Fax: 01224 438165
Email: tisu@abdn.ac.uk
<http://www.chartrials.abdn.ac.uk/tisu>**

<<TISU HEADED PAPER>>
6 month post randomisation letter

<< Date >>

<<Participant Title & Name>>

TISU STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Participant Title & Name>>

The TISU STUDY

It is now approximately six months since you joined the TISU study - many thanks for taking part. We are keen to find out how you have been getting on since you joined the study so please find enclosed the final of the three follow-up questionnaires.

Although some of the questions may not seem relevant, we would like you to complete the questionnaire as fully as you can. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively please contact the TISU Study Office on 01224 xxxxxx or email: tisu@abdn.ac.uk.

The questionnaire can be returned in the reply-paid envelope provided (no stamp is required). Please note that ALL the information you give will be treated with the strictest confidence.

Thank you again for taking part in the TISU study. Your views and information about your recovery are very important to improving the management of patients that have ureteric stones in the future.

With our very best wishes,

XXXXXXXXX
Trial Manager

TISU – text to be sent to participants who request email contact to complete 6 month questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY

It is now approximately six months since you joined the TISU study - many thanks for taking part. We are keen to find out how you have been getting on since you joined the study. Please click on the link below to complete the third (and final) online questionnaire.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the questionnaire online. Your password is **XXXXXXXXXX**

Although some of the questions may not seem relevant, we would like you to complete the questionnaire as fully as you can. Your experience is relevant for the study and the information you provide is very important.

If you have any problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, you can contact the TISU study office on 01224 43xxxx or email tisu@abdn.ac.uk.

We would like to thank you very much for taking part in the TISU study and for completing the questionnaire as your views and information about your recovery are very important to improving the management of patients that have ureteric stones in the future.

With our very best wishes

XXXXXXXXXX
Trial Manager

<<TISU HEADED PAPER>>
6 month reminder letter

<< Date >>

<<Participant Title & Name>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>
<<Postcode>>

TISU STUDY No. <<.....>>

Dear <<Participant Title & Name>>

The TISU STUDY

It is now over 6 months since you kindly agree to take part in the TISU study. We sent you the last of the three follow-up questionnaires a few weeks ago, but unfortunately we have not yet received your answers. We are keen to find out how you have been getting on since you agreed to take part in the study.

You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer the enclosed questionnaire and return it in the pre-paid envelope (no need for a stamp). If your reply is already in the post, thank you for your help and our apologies for this reminder.

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 XXXXXX or email e-mail: tisu@abdn.ac.uk

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager

TISU – reminder text to be sent to participants who request email contact to complete 6 month questionnaire online

Dear <<Participant Title & Name>>

The TISU STUDY

It is now over 6 months since you kindly agree to take part in the TISU study. We sent you the link to complete the third and final online follow-up questionnaires a few weeks ago, but unfortunately we have not yet received your answers.

We are keen to find out how you have been getting on since you agreed to take part in the study. You may not think the questionnaire is relevant to you. Perhaps your treatment didn't work out as planned, or your stone passed very quickly and it all seems like a long time ago. Whatever happened, every person's experience is relevant to the results of the study so we are really interested to hear from you.

We would therefore be very grateful if you could spare the time to answer questionnaire on the link below.

Please click on this link xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx to complete the questionnaire online. Your password is **XXXXXXXXXX**

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. Alternatively, please contact the TISU Study Office on 01224 XXXXXX or email e-mail: tisu@abdn.ac.uk.

All the information you provide will be treated with the strictest confidence.

With our very best wishes,

Trial Manager



Study Number

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BASELINE CASE REPORT FORM

PATIENT DETAILS (Sticker may be used below)

Title Mr Mrs Miss Ms Other

First name:

Surname:

Address:

Postcode:

Mobile telephone number (or other contact number)

E-mail Address:

Date of birth:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Gender:

Male Female

NHS number:

| | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | | | | | |
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CHI number (Scotland only):

| | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

CONSULTANT DETAILS

Initials:

Surname:

GP DETAILS

Initials:

Surname:

Address:

CLINICAL DATA

Date of baseline assessment

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Presence of stone confirmed by CTKUB

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

MEDICAL HISTORY

Start of current stone episode

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Detail all treatments to date for this stone episode

Treatment

Tick if yes

Date of treatment

Percutaneous insertion of nephrostomy tube (M13)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Antegrade insertion of stent into ureter (M33)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Endoscopic insertion of stent into ureter (M29)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Endoscopic removal of stent from ureter (M29)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Medical Expulsive Treatment (MET)

Date started

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Date stopped

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Other

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

If other treatment, please specify

Current analgesic medications

Yes

No

If yes, please select type of medication:

Non-steroidal

Opiate

Other

If other, please specify

RANDOMISATION INFORMATION

Telephone Randomisation Service Number:

0800 2802 307

Ureteric Stone Size (*largest dimension*):

 mm

What is the stone volume?
(If available)

 mm³

Stone Location:

Upper Ureter

Middle Ureter

Lower Ureter

Participant Study No:

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Randomised to:

ESWL

Ureteroscopic
treatment

Planned treatment date

| | |
|---|---|
| D | D |
|---|---|

 /

| | |
|---|---|
| M | M |
|---|---|

 /

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|



Study number

| | | | | |
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|--|--|--|--|--|

TREATMENT CRF

Date of admission

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Date of treatment

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Date of discharge

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Q1 HAS PARTICIPANT ATTENDED HOSPITAL DUE TO HIS/HER STONE SINCE RANDOMISATION

Yes No (if no, go to question 2)

If yes please provide details of each hospital visit:

| | | | | | | | | | | | | | | | | | | | |
|-----------------------|--|---|-------------------|---|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|
| | Date of admission | | Date of discharge | | | | | | | | | | | | | | | | |
| Hospital visit | <table border="1" style="display: inline-table;"> <tr><td style="width: 25px; height: 25px;">D</td><td style="width: 25px; height: 25px;">D</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="width: 25px; height: 25px;">M</td><td style="width: 25px; height: 25px;">M</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td></tr> </table> | D | D | M | M | Y | Y | Y | Y | / | <table border="1" style="display: inline-table;"> <tr><td style="width: 25px; height: 25px;">D</td><td style="width: 25px; height: 25px;">D</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="width: 25px; height: 25px;">M</td><td style="width: 25px; height: 25px;">M</td></tr> </table> <table border="1" style="display: inline-table; margin-left: 10px;"> <tr><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td><td style="width: 25px; height: 25px;">Y</td></tr> </table> | D | D | M | M | Y | Y | Y | Y |
| D | D | | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | | |
| D | D | | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | | |

Was further imaging performed? Yes No

If yes:

Plain X-ray KUB Ultrasound CT KUB IVU Other

If other, please specify:

Did stone pass spontaneously? Yes No

Further interventions since randomisation (before allocated trial treatment) Yes No

If yes, please specify:

| | yes | Date of intervention | | | | | | | |
|---|--------------------------|----------------------|---|---|---|---|---|---|---|
| Percutaneous insertion of nephrostomy tube (M13) | <input type="checkbox"/> | D | D | M | M | Y | Y | Y | Y |
| Antegrade insertion of ureteric stent(M33) | <input type="checkbox"/> | D | D | M | M | Y | Y | Y | Y |
| Therapeutic ureteroscopic operations (includes calculus fragmentation/removal)(M27) | <input type="checkbox"/> | D | D | M | M | Y | Y | Y | Y |
| Endoscopic insertion of stent into ureter (M29) | <input type="checkbox"/> | D | D | M | M | Y | Y | Y | Y |
| Endoscopic removal of stent from ureter (M29) | <input type="checkbox"/> | D | D | M | M | Y | Y | Y | Y |

ESWL of calculus of ureter (M31)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Other

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

If other treatment, please specify:

TREATMENT DAY

Q2 HAS ANY PRE-TREATMENT IMAGING BEEN CARRIED OUT?

Yes No

Test

Plain X-ray KUB

Ultrasound

CT KUB

IVU

STONE STILL PRESENT? Yes No

If No, stop here.

CURRENT STONE POSITION

Upper ureter Middle ureter Lower ureter

Q3. TREATMENT TECHNIQUE

Please confirm which treatment was carried out:

| | | | |
|---------------------------|------------------------------|--------------------------------|--|
| ESWL | <input type="checkbox"/> | Ureteroscopic treatment | <input type="checkbox"/> |
| Number of shocks | <input type="text"/> | Rigid <input type="checkbox"/> | Flexi <input type="checkbox"/> Both <input type="checkbox"/> |
| Time started (24h clock) | <input type="text"/> | Stent required | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Time finished (24h clock) | <input type="text"/> | | |
| Total time of treatment | <input type="text"/> minutes | | |

| | | |
|---------------------------------|------------------------------|-----------------------------|
| Treatment completed | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| If not, please explain why not: | | |

Please record any additional hospital visits on the Supplementary hospital visit form

POST-TREATMENT COMPLICATIONS BEFORE DISCHARGE

Any complications during hospital visit? Yes No

ESWL

Failure of treatment
Migration of stone
Infection
Pain requiring admission
Renal haematoma
Other

Ureteroscopy

Failure of treatment
Stent required
Infection
Pain requiring admission
Ureteric perforation
Other

If other, please give details:

** Please complete a Serious Adverse Event form if the patient suffers a medically significant serious complication, is admitted to hospital or their hospitalisation admission is prolonged and if the patient dies (any reason). Further intervention to facilitate stone clearance will NOT be recorded as an SAE.*



Study number

SECOND ESWL TREATMENT CRF (record any further treatments on 8 week or 6 month CRF)

Date of admission

Date of treatment

Date of discharge

WHAT PRE-TREATMENT IMAGING HAS BEEN CARRIED OUT SINCE FIRST TREATMENT?

Test

Plain X-ray KUB

Ultrasound

CT KUB

IVU

STONE STILL PRESENT? Yes No

If No, stop here.

Q1. TREATMENT DETAILS

ESWL

Number of shocks

Time started (24h clock) hours minutes
 Time finished (24h clock) hours minutes

Total time of treatment minutes

Treatment completed Yes No

If treatment not complete, please explain why not:

Q2. POST-TREATMENT COMPLICATIONS BEFORE DISCHARGE*

- | | | | |
|----------------------|--------------------------|--------------------------|--------------------------|
| Failure of treatment | <input type="checkbox"/> | Migration of stone | <input type="checkbox"/> |
| Infection | <input type="checkbox"/> | Pain requiring admission | <input type="checkbox"/> |
| Renal haematoma | <input type="checkbox"/> | Other | <input type="checkbox"/> |

If other, please give details

*Please complete a serious adverse event form if the patient is admitted to hospital or their hospitalisation admission is prolonged as a result of a complication (e.g. Infection) resulting from their ureteric stone treatment or if the patient dies (any reason). If the participant requires further treatment to clear the ureteric stone, please **record this on the 8 week or 6 month CRF as appropriate**



Study Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

8 WEEK CASE REPORT FORM

Date of completion

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Q1 Treatment complete? Yes No

Q2 Has the stone cleared? Yes No Don't know

If yes, when did the stone clear:

(If you are not sure please give an approximate date)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Q3 Has participant attended hospital due to the stone since his/her trial treatment (i.e. up to 2 ESWL/ Ureteroscopy)

Yes No (if No, please go to Question 4)

If yes please provide details of each hospital visit:

Please record any additional hospital visits on the Supplementary hospital visit form

| | Date of Admission | Date of Discharge | | | | | | | | | | | | | | | | |
|-----------------------|---|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hospital visit | <table border="1" style="display: inline-table; margin-right: 5px;"> <tr> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">D</td> </tr> </table> <table border="1" style="display: inline-table; margin-right: 5px;"> <tr> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> </tr> </table> <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> </tr> </table> | D | D | M | M | Y | Y | Y | Y | <table border="1" style="display: inline-table; margin-right: 5px;"> <tr> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">D</td> </tr> </table> <table border="1" style="display: inline-table; margin-right: 5px;"> <tr> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> </tr> </table> <table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> </tr> </table> | D | D | M | M | Y | Y | Y | Y |
| D | D | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | |
| D | D | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | |

Was further imaging performed? Yes No

If yes:

Plain X-ray KUB Ultrasound CT KUB IVU Other

If other, please specify:

Further Interventions since treatment

Has the patient received any other ureteric stone treatment (excluding randomised treatment)?

Yes No

If yes, please specify date of intervention:

| | Yes | Date of intervention | | | |
|---|--------------------------|---|---|---|--|
| Percutaneous insertion of nephrostomy tube (M13) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Antegrade insertion of stent into ureter (M33) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Therapeutic ureteroscopic operations (includes calculus fragmentation/removal)(M27) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Endoscopic insertion of stent into ureter (M29) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Endoscopic removal of stent from ureter (M29) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| ESWL of calculus of ureter (M31) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Other | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |

If other treatment, please specify

Any complications during hospital visit*

Yes No

ESWL

- Failure of treatment
- Migration of stone
- Infection
- Pain requiring admission
- Renal haematoma
- Other

Ureteroscopy

- Failure of treatment
- Stent required
- Infection
- Pain requiring admission
- Ureteric perforation
- Other

If other, please give details:

****Please complete a Serious Adverse Event form if the patient suffers a medically significant serious complication, is admitted to hospital or their hospitalisation admission is prolonged and if the patient dies (any reason). Further interventions to facilitate stone clearance will NOT be recorded as an SAE.***

Q4 Further treatment/surgery planned

Is further treatment/surgery planned for persistent ureteric stone? Yes No

If yes, please indicate what is intended (*please tick all that are appropriate*):

- | | | | |
|--|---|---|---|
| <p>Percutaneous insertion of nephrostomy tube (M13)</p> <p>Endoscopic removal of stent from ureter (M29)</p> <p>ESWL of calculus of ureter (M31)</p> | <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> | <p>Endoscopic insertion of stent into ureter (M29)</p> <p>Antegrade insertion of stent into ureter (M33)</p> <p>Therapeutic Ureteroscopic operations (includes calculus fragmentation/removal)(M27)</p> | <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> |
|--|---|---|---|

| | | | | | | | | | | |
|------------------|---------------------------------|--------------------|---|---|---|---|---|---|---|---|
| <p>α-blocker</p> | <p><input type="checkbox"/></p> | <p>Start date</p> | D | D | M | M | Y | Y | Y | Y |
| | | <p>Finish date</p> | D | D | M | M | Y | Y | Y | Y |

Other

If other, please give details:



Study Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

6 MONTH CASE REPORT FORM

Date of completion

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Q1 Treatment complete? Yes No

Q2 Has the stone cleared? Yes No Don't know

If yes, when did the stone clear:

(If you are not sure please give an approximate date)

| | |
|---|---|
| D | D |
|---|---|

| | |
|---|---|
| M | M |
|---|---|

| | | | |
|---|---|---|---|
| Y | Y | Y | Y |
|---|---|---|---|

Q3 Has participant attended hospital due to the stone in the past 4 months (since 8 week follow up and randomisation)

Yes No (if No, please go to Question 4)

If yes please provide details of each hospital visit:

Please record any additional hospital visits on the Supplementary hospital visit form

| | Date of Admission | | | | Date of Discharge | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|---|---|---|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hospital visit | <table border="1"><tr><td>D</td><td>D</td></tr></table> | D | D | <table border="1"><tr><td>M</td><td>M</td></tr></table> | M | M | <table border="1"><tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> | Y | Y | Y | Y | <table border="1"><tr><td>D</td><td>D</td></tr></table> | D | D | <table border="1"><tr><td>M</td><td>M</td></tr></table> | M | M | <table border="1"><tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> | Y | Y | Y | Y | <table border="1"><tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table> | Y | Y | Y | Y |
| D | D | | | | | | | | | | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | | | | | | | | | | |
| D | D | | | | | | | | | | | | | | | | | | | | | | | | | | |
| M | M | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | | | | | | | | | | |
| Y | Y | Y | Y | | | | | | | | | | | | | | | | | | | | | | | | |

Was further imaging performed? Yes No

If yes:

Plain X-ray KUB Ultrasound CT KUB IVU Other

If other, please specify:

Further Interventions since treatment

Has the patient received any other ureteric stone treatment (excluding randomised treatment)?

Yes No

If yes, please specify date of intervention:

| | Yes | Date of intervention | | | |
|---|--------------------------|---|---|---|--|
| Percutaneous insertion of nephrostomy tube (M13) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Antegrade insertion of stent into ureter (M33) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Therapeutic ureteroscopic operations (includes calculus fragmentation/removal)(M27) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Endoscopic insertion of stent into ureter (M29) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Endoscopic removal of stent from ureter (M29) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| ESWL of calculus of ureter (M31) | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |
| Other | <input type="checkbox"/> | <input type="text" value="D"/> <input type="text" value="D"/> | <input type="text" value="M"/> <input type="text" value="M"/> | <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> | |

If other treatment, please specify

Any complications during hospital visit*

Yes No

ESWL

- Failure of treatment
- Migration of stone
- Infection
- Pain requiring admission
- Renal haematoma
- Other

Ureteroscopy

- Failure of treatment
- Stent required
- Infection
- Pain requiring admission
- Ureteric perforation
- Other

If other, please give details:

****Please complete a Serious Adverse Event form if the patient suffers a medically significant serious complication, is admitted to hospital or their hospitalisation admission is prolonged and if the patient dies (any reason). Further interventions to facilitate stone clearance will NOT be recorded as an SAE.***

Q4 Further treatment/surgery planned

Is further treatment/surgery planned for persistent ureteric stone? Yes No

If yes, please indicate what is intended (*please tick all that are appropriate*):

- | | | | |
|--|---|---|---|
| <p>Percutaneous insertion of nephrostomy tube (M13)</p> <p>Endoscopic removal of stent from ureter (M29)</p> <p>ESWL of calculus of ureter (M31)</p> | <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> | <p>Endoscopic insertion of stent into ureter (M29)</p> <p>Antegrade insertion of stent into ureter (M33)</p> <p>Therapeutic Ureteroscopic operations (includes calculus fragmentation/removal)(M27)</p> | <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> |
|--|---|---|---|

α-blocker

| | | | | | | | | | |
|--------------------------|-------------|---|---|---|---|---|---|---|---|
| <input type="checkbox"/> | Start date | D | D | M | M | Y | Y | Y | Y |
| | Finish date | D | D | M | M | Y | Y | Y | Y |

Other

If other, please give details:



Study number

SUPPLEMENTARY HOSPITAL VISIT CRF

Hospital Visit

Date of Admission Date of Discharge

Was further imaging performed? Yes No

Plain X-ray KUB
 Ultrasound
 CT KUB
 IVU
 Other

If other, please specify:

Further Interventions since allocated trial treatment

Has the patient received any other ureteric stone treatment (excluding allocated treatment)?

Yes No

If yes, please specify date of intervention:

| | Yes | Date of intervention | | | |
|---|--------------------------|----------------------|----------------------|----------------------|----------------------|
| | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Percutaneous insertion of nephrostomy tube (M13) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Antegrade insertion of stent into ureter (M33) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Therapeutic ureteroscopic operations (includes calculus fragmentation/removal)(M27) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Endoscopic insertion of stent into ureter (M29) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Endoscopic removal of stent from ureter (M29) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| ESWL of calculus of ureter (M31) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Other | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

If other treatment, please specify

Any complications during hospital visit*

Yes No

ESWL

- Failure of treatment
- Migration of stone
- Infection
- Pain requiring admission
- Renal haematoma
- Other

Ureteroscopy

- Failure of treatment
- Stent required
- Infection
- Pain requiring admission
- Ureteric perforation
- Other

If other, please give details:

****Please complete a Serious Adverse Event form if the patient suffers a medically significant serious complication, is admitted to hospital or their hospitalisation admission is prolonged and if the patient dies (any reason). Further interventions to facilitate stone clearance will NOT be recorded as an SAE.***

TISU INELIGIBLE OR DECLINED FORM

Outline data on patients who are ineligible or who decline participation

Q1 Date of attempted recruitment / /

Q2 Year of Birth

Gender (please tick) Male Female

Q3 Reasons for non-inclusion – please tick all that apply

Q3a Patient declined Reason (if provided)

OR patient declined to give a reason

Q3b Clinical reason:

- Pregnant
- Stone not confirmed by CTKUB
- Bilateral ureteric stone(s)
- Abnormal urinary tract anatomy
- Patient unable to understand or complete trial documentation
- Other reason *

* If other, please state:

Signature: _____

Print Name: _____



Serious Adverse Event/ Death Report Form

To be completed for any Serious Adverse Event (SAE) that is:

- related (resulted from administration of any of the research procedures) and
- unexpected (unexpected events are not listed in section 4 in the protocol as a possible expected serious occurrence)

ALL deaths must be recorded using this Report Form

Please Note:

- Non-serious events will not be collected or reported
- Planned hospital visits for conditions other than those associated with the ureteric stone will not be collected or reported
- Hospital visits (planned or unplanned) associated with further interventions to facilitate ureteric stone clearance will not be recorded as an SAE

Study No

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Report Date

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Q1. Type of event

(cross all appropriate to adverse event – if any boxes are crossed the adverse event is “serious”)

Patient died

Readmission

Prolongation of existing hospitalization

Persistent or significant disability or incapacity

Life threatening

Considered medically significant by the investigator

Q2. Date of event

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Q3. Brief details of adverse event

Q4. Is this an “expected” serious adverse event?

Yes

No

Q5. Other relevant history (e.g. diagnostics, allergies, etc)

Q6. Place where adverse event took place/detected

Q7. Details of any intervention required

Assessment of whether the event was caused by trial participation:

Q7a. Is it reasonably likely that the adverse event was caused by taking part in TISU?

Yes

No

Q7b. Why?

Q8. Name and position of person making this judgement

Q8a. Date of assessment

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | / | M | M | / | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|



CHANGE OF STATUS

Study number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Date of withdrawal

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| D | D | \ | M | M | \ | Y | Y | Y | Y |
|---|---|---|---|---|---|---|---|---|---|

Reason for withdrawal

Please tick this box if participant has decided to withdraw

Please state reason for withdrawal in the box below

| |
|--|
| |
|--|

Any medical reason for withdrawal? (state reason)

| |
|--|
| |
|--|

What is participant withdrawing from?

All treatment

Yes

No

Completing questionnaires

Yes

No

Relevant outcome data being collected
(via hospital and GP records)

Yes

No

Contact by telephone

Yes

No