

Ineligible or Declined

Outline data on patients who are ineligible or who decline participation

Q1 Date of attempted recruitment DD/MM/YY / /

Q2 Gender

Male Female

Q3 Age

Q4 Centre

Q5 Reasons for non-inclusion - tick all that apply

- Arthroscopic lavage clearly indicated
- Arthroplasty clearly indicated
- Clear contra-indication to anaesthesia
- Patient does not understand English
- Patient unable to complete follow-up questionnaires
- Patient does not want to participate in the study:
 - does not like the idea of the study
 - does not like the idea of a placebo
- Other

If other, please state:

Signature: _____

STUDY No.

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CONFIDENTIAL

KORAL STUDY

***ARTHROSCOPIC LAVAGE IN THE TREATMENT OF
OSTEOARTHRITIS OF THE KNEE***

PARTICIPANT DETAILS FORM

Thank you for helping us with our research

We would be very grateful if you could complete and return this form.



KNEE OSTEOARTHRITIS:
ROLE OF ARTHROSCOPIC LAVAGE

To be completed on withdrawal from the study

Study No

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1. **Date of withdrawal (dd/mm/yy)**

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Reason for withdrawal

2. **Participant decided to withdraw (state reason)**

--

3. **Any medical reasons for withdrawal? (state reason)**

--

4. **Continued use of data**

Does the participant agree to relevant data being collected in the future through central sources (eg hospital notes)?

Yes

No

Clinical data sheet



Study No

Date of clinic (DD/MM/YY) / /

1. Study Knee Right Left
 2. ASA Grade – fit for surgery? Yes No

3. X-ray grading (Kellgren-Lawrence) 0 1
 2 3
 4 (ineligible)
 4. Mechanical Symptoms present? Yes (and therefore ineligible) No

5. Range of motion Hyperextension ° Neutral Yes No
 Flexion ° If No, fixed flexion deformity °

6. Effusion 0 none ++ mod
 + mild +++ severe

7. Limb alignment 1 (with patient standing)
 Normal (medial malleoli and medial femoral condyles touch) Yes No
 Varus Yes No If Yes, gap between medial femoral condyles cms
 Valgus Yes No If Yes, gap between medial malleoli cms

8. Limb alignment 2 Femoro-tibial angle °

9. Height cms 10. Weight kgs

MEDICAL MANAGEMENT

Date

Study No

- YES**
1. **Analgesia**
- Simple
- NSAID
- Other

- YES**
2. **Support**
- Walking stick
- Elastic knee brace
- Other

If other, specify

3. **Heat or Ice**

4. **Lifestyle modification advice**

5. **Exercise**

Referral

Exercise sheet

6. **Injection**

Steroid

HA

7. **Glucosamine**

8. **Chondroitin**

9. **Other**

If other, specify

MEDICAL MANAGEMENT FOLLOW-UP CLINIC



Study No

Date of clinic (DD/MM/YY) / /

1. Study Knee
Right
Left

2. Range of motion
Hyperextension ° Neutral Yes No
Flexion ° If No, fixed flexion deformity °

3. Effusion
0 none ++ mod
+ mild +++ severe

4. Weight kgs

5. Any other treatment/surgery planned?
Yes
No

6a. If yes, what?

6b. If yes, when?

7. Any clinical follow-up planned?
Yes
No

7a. If yes, what?

7b. If yes, when?

8. Any change of symptoms?

RANDOMISED TO SURGERY - PARTICIPANT DETAILS



KNEE OSTEOARTHRITIS:
ROLE OF ARTHROSCOPIC LAVAGE

Date of clinic

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
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1. Study number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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2. Hospital number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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3. Surname

<input type="text"/>

4. First Name(s)

<input type="text"/>

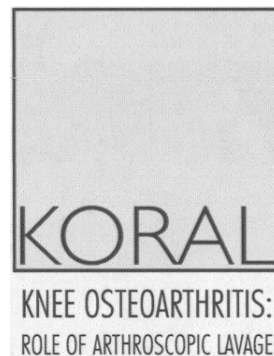
5. Address

<input type="text"/>
<input type="text"/>
<input type="text"/>

6. Surgery code

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Anaesthetic details



Study No

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1 **Grade of anaesthetist**

Consultant

Associate Specialist/Staff Grade

Specialist Trainee

2 **Patient's ASA grade**

I

II

III or above (*ineligible*)

3 **Induction agent**

Propofol

Thiopentone

Other

4 **OPIOID**

Short acting (Fentanyl/Alfentanil)

Long Acting (Morphine)

5 **Maintenance**

Nitrous Oxide

Volatile

Volatile

6 **Analgesia (post-op)**

NSAID

Paracetamol

OPIOID

7 **Airway**

MASK

LMA

Tracheal Tube

8 **Time into Anaesthetic Room (*hh:mm*)** :

9 **Time into Theatre** :

10 **Time into Recovery** :

Surgical details

If randomised to arthroscopic lavage, complete all pages. If randomised to placebo operation, complete pages 1 and 2 only.



Study No

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Date of surgery (DD/MM/YY)

		/			/		
--	--	---	--	--	---	--	--

Randomised to:

Arthroscopy

Placebo operation

Tourniquet

Yes

No

If Yes

Mins

mmHg

EUA:

Hyperextension

Extension deficit

Flexion

Effusion

0 none

+ mild

++ mod

+++ severe

Lachman

0-2mm

3-5mm

6-9mm

≥10mm

Firm

Not Firm

Pivot

0 none

Shift

+ glide

++clunk

+++ gross

MCL

0-2mm

3-5mm

6-9mm

≥10mm

LCL

0-2mm

3-5mm

6-9mm

≥10mm

PCL

0-2mm

3-5mm

6-9mm

≥10mm

Other

--

Grade of surgeon:

Confirm Consultant (as per protocol)

Date of hospital discharge (DD/MM/YY)

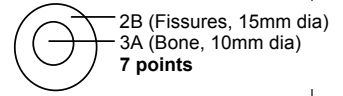
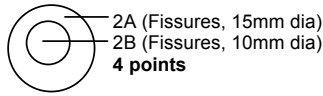
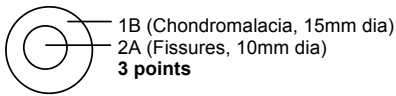
		/			/		
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LA	20ml 0.5% Marcain
Dressing	Steristrips <input type="checkbox"/> Suture <input type="checkbox"/> opsite, gauze, wool, crepe
Post-Op	Routine care, mobilise ASAP. Reduce dressing to DTG at discharge
Follow-up	<input type="text"/> Physio <input type="text"/>
Other	<input type="text"/>
Signed	<input type="text"/>

Modified Noyes Rating

Lesion Score		10mm	15mm
1 Chondromalacia:	A soft,	1	2
	B softening, indentation	1	2
2 Open Lesion thickness	A Fissure/fragmentation half thickness	2	3
	B Fissure/fragmentation full thickness	3	6
3 Bone	A exposed,	5	10
	B bone cavity	5	10

Complex lesions - Examples



Anatomical Score

Score

Patella	<input type="text"/>	}	=	}	Total score
+ Femoral sulcus	<input type="text"/>				
Medial Femur	<input type="text"/>	}	=		
+ Medial Tibia	<input type="text"/>				
Lateral Femur	<input type="text"/>	}	=		
+ Lateral Tibia	<input type="text"/>				

Was debridement done?

Yes

No

If yes, please indicate type of debridement:

Miniscus

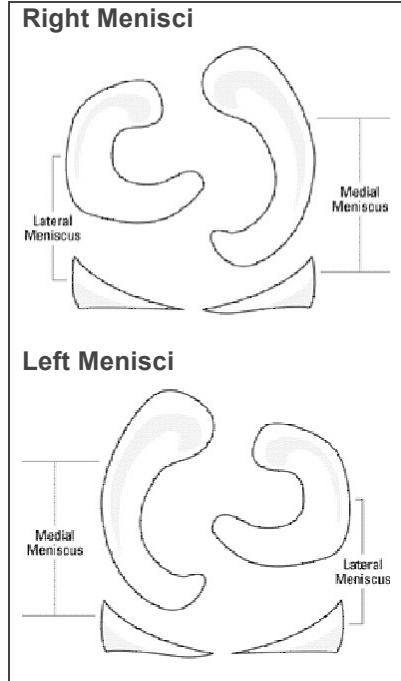
Articular cartilage

Other (please describe)

Subjective findings

ARTHROSCOPY Incisions : Medial, lateral, lateral suprapatellar Findings and Action

Patello-femoral	
Gutters	
Medial	
Lateral	
Medial Meniscus	
Lateral Meniscus	
ACL/PCL/Notch	

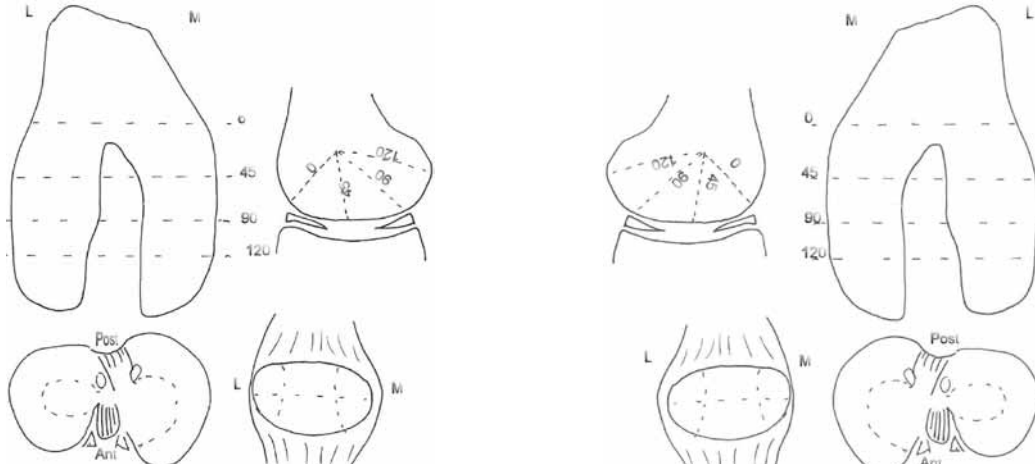


ICRS rating

Draw chondral lesions on appropriate diagram, then record lesion grade and size

Right Knee Joint Surfaces

Left Knee Joint Surfaces



ICRS Grade 0 – Normal

ICRS Grade 1 – Nearly Normal
Superficial lesions, Soft indentation (A) and/or superficial fissures and cracks (B)

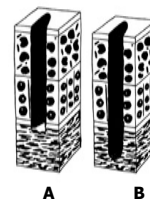
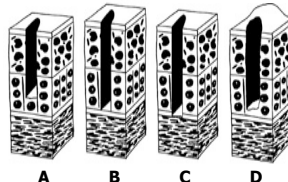
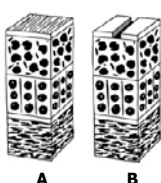
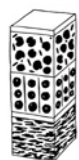
ICRS Grade 2 – Abnormal
 Lesions extending down to <50% of cartilage depth

ICRS Grade 3 – Severely Abnormal

Cartilage defects extending down >50% of cartilage depth (A) as well as down to calcified layer (B) and down to Blisters are included in this Grade (D)

ICRS Grade 4 – Severely Abnormal

Osteochondral injuries, lesions extending just through the subchondral boneplate (A) or deeper defects down into trabecular bone (B). Defects that have been drilled are regarded as osteochondral defects and classified as ICRS-C



Surgical follow-up clinic



Study No

Date of clinic (DD/MM/YY) / /

1. Study Knee

Left

Right

2. Wound healed?

Yes

No

If no, please
give details

3. Any evidence of inflammation?

No

Yes

If yes, please
give details

4. Have there been problems since surgery over and above normal post-operative issues (eg infection treated by antibiotics, persistent discharge)?

No

Yes

If yes, please
give details

5. Was the patient re-admitted to hospital?

No

Yes

If yes, please
give details

6. Was the patient discharged on the day of surgery?

Yes

No

If no, please
give details

7. Range of motion

Hyperextension	<input type="text"/> °	Extension deficit (0 if neutral)	<input type="text"/> °	Flexion	<input type="text"/> °
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8. Effusion

0 none	<input type="checkbox"/>	++ mod	<input type="checkbox"/>
+ mild	<input type="checkbox"/>	+++ severe	<input type="checkbox"/>

9. Any other treatment/surgery planned?

Yes

No

9a. **If yes, what?**

9b. **If yes, when?**

10. Any **clinical follow-up** planned?

Yes

No

10a. **If yes, what?**

10b. **If yes, when?**

There will be additional patient follow-up (by postal questionnaire) – these questionnaires will be administered by the KORAL team.

Serious Adverse Event Report



To be completed for any serious adverse events

Study No

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1. **Date of report (dd/mm/yy)**

--	--	--	--	--	--

2. **Name of person initially reporting adverse event**

--

Contact details Address

--

Telephone

--

Email

--

PATIENT DETAILS

3. **Patient's Initials**

--

4. **Date of birth**

--	--	--	--	--	--

5. **Hospital number**

--

6. **Sex**

Male

Female

7. **Place where adverse event took place/detected**

--

8. **Date of event**

--	--	--	--	--	--

9 Brief details of adverse event

10. Cross all appropriate to adverse event – if any boxes are crossed the adverse event is “serious”.

- Patient died
- Involved or prolonged inpatient hospitalisation
- Involved persistent or significant disability or incapacity
- Life threatening

11. Is this serious adverse event one of XXXXXXXX (eg post-operative infection) and therefore an “expected” serious adverse event?

- Yes
- No

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

Assessment of whether event was caused by trial participation

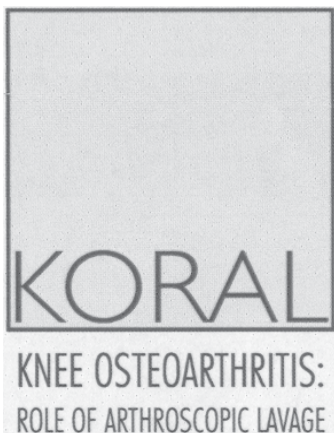
13. Is it reasonably likely that the adverse event was caused by taking part in KORAL

- Yes
- No

14. Why

15. Name and position of person making this judgment

16. Any subsequent information



STUDY No.

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CONFIDENTIAL

KORAL STUDY

***ARTHROSCOPIC LAVAGE FOR TREATMENT OF
OSTEOARTHRITIS OF THE KNEE***

BASELINE QUESTIONNAIRE

***Thank you for helping us with research into osteoarthritis
of the knee. We would be very grateful if you could
complete and return this questionnaire.***

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

The following questions ask about problems which may have been caused by your knee during **the past 4 weeks**.

A1. During the past 4 weeks how would you describe the pain you have from your knee?

(Cross **ONE** box only)

None	<input type="checkbox"/>
Very mild	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

A2. During the past 4 weeks have you had any trouble with washing and drying yourself (all over) because of your knee?

(Cross **ONE** box only)

No trouble at all	<input type="checkbox"/>
Very little trouble	<input type="checkbox"/>
Moderate trouble	<input type="checkbox"/>
Extreme trouble	<input type="checkbox"/>
Impossible to do	<input type="checkbox"/>

A3. During the past 4 weeks have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you tend to use).

(Cross **ONE** box only)

No trouble at all	<input type="checkbox"/>
Very little trouble	<input type="checkbox"/>
Moderate trouble	<input type="checkbox"/>
Extreme difficulty	<input type="checkbox"/>
Impossible to do	<input type="checkbox"/>

A4. During the past 4 weeks for how long have you been able to walk before the pain from your knee becomes severe? (with or without a stick).

(Cross **ONE** box only)

No pain at all, or no pain for more than 30 mins	<input type="checkbox"/>
16 to 30 mins	<input type="checkbox"/>
5 to 15 mins	<input type="checkbox"/>
Around the house only	<input type="checkbox"/>
Not at all - severe on walking	<input type="checkbox"/>

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

A5. During the past 4 weeks after a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

(Cross **ONE** box only)

Not at all painful	<input type="checkbox"/>
Slightly painful	<input type="checkbox"/>
Moderately painful	<input type="checkbox"/>
Very painful	<input type="checkbox"/>
Unbearable	<input type="checkbox"/>

A6. During the past 4 weeks have you been limping when walking, because of your knee?

(Cross **ONE** box only)

Rarely/never	<input type="checkbox"/>
Sometimes or just at first	<input type="checkbox"/>
Often, not just at first	<input type="checkbox"/>
Most of the time	<input type="checkbox"/>
All of the time	<input type="checkbox"/>

A7. During the past 4 weeks could you kneel down and get up again afterwards? (thinking of your knee)

(Cross **ONE** box only)

Yes, easily	<input type="checkbox"/>
With little difficulty	<input type="checkbox"/>
With moderate difficulty	<input type="checkbox"/>
With extreme difficulty	<input type="checkbox"/>
No, impossible	<input type="checkbox"/>

A8. During the past 4 weeks have you been troubled by pain from your knee in bed at night?

(Cross **ONE** box only)

No, never	<input type="checkbox"/>
Only 1 or 2 nights	<input type="checkbox"/>
Some nights	<input type="checkbox"/>
Most nights	<input type="checkbox"/>
Every night	<input type="checkbox"/>

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

A9. During the past 4 weeks how much has pain from your knee interfered with your usual work (including housework)?

(Cross **ONE** box only)

Not at all	<input type="checkbox"/>
A little bit	<input type="checkbox"/>
Moderately	<input type="checkbox"/>
Greatly	<input type="checkbox"/>
Totally	<input type="checkbox"/>

A10. During the past 4 weeks have you felt that your knee might suddenly "give way" or let you down?

(Cross **ONE** box only)

Rarely/never	<input type="checkbox"/>
Sometimes or just at first	<input type="checkbox"/>
Often, not just at first	<input type="checkbox"/>
Most of the time	<input type="checkbox"/>
All of the time	<input type="checkbox"/>

A11. During the past 4 weeks could you do the household shopping on your own? (thinking of your knee)

(Cross **ONE** box only)

Yes, easily	<input type="checkbox"/>
With little difficulty	<input type="checkbox"/>
With moderate difficulty	<input type="checkbox"/>
With extreme difficulty	<input type="checkbox"/>
No, impossible	<input type="checkbox"/>

A12. During the past 4 weeks could you walk down a flight of stairs? (thinking of your knee)

(Cross **ONE** box only)

Yes, easily	<input type="checkbox"/>
With little difficulty	<input type="checkbox"/>
With moderate difficulty	<input type="checkbox"/>
With extreme difficulty	<input type="checkbox"/>
No, impossible	<input type="checkbox"/>

SECTION B – DESCRIBING YOUR OWN HEALTH TODAY

The next two sections are about your general health.

By placing a cross (X) in one box in each group below, please indicate which statement best describes your own health state today. Do not X more than one box in each group.

B1. Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

B2. Self-Care

I have no problems with self care

I have some problems washing and dressing myself

I am unable to wash myself

B3. Usual activities (eg work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

B4. Pain / Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

B5. Anxiety / Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

*Best imaginable
health state*

100



90



80



70



60



50



40



30



20



10



0

*Worst imaginable
health state*

*Please indicate on this scale
how good or bad your own health
state is today.*

*The best health state you can
imagine is marked 100 and the
worst health state you can imagine
is marked 0.*

*Please draw a line from the box below
to the point on the scale that best
indicates how good or bad your health
state is today.*

Your own
health state
today

SECTION C – GENERAL HEALTH SF12 ©

The following questions ask for your views about your health **in the last 4 weeks**, how you feel and how well you are able to do your usual activities.

Answer every question by placing a cross in one box only. If you are unsure about how to answer any questions please give the best answer you can.

C1. In general, would you say your health is:

(Cross **ONE** box only)

Excellent

Very good

Good

Fair

Poor

C2. During a typical day does your health limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?

(Cross **ONE** box only)

Yes, limited a lot

Yes, limited a little

No, not limited at all

C3. During a typical day does your health limit you in climbing several flights of stairs? If so, how much?

(Cross **ONE** box only)

Yes, limited a lot

Yes, limited a little

No, not limited at all

SECTION C – GENERAL HEALTH SF12 ©

C4. During the past 4 weeks, how often have you accomplished less than you would have liked in your work or other regular daily activities as a result of your physical health?

(Cross **ONE** box only)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C5. During the past 4 weeks, how often have you been limited in performing any kind of work or other regular daily activities as a result of your physical health?

(Cross **ONE** box only)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C6. During the past 4 weeks, how often have you accomplished less than you would have liked in your work or any other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Cross **ONE** box only)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

SECTION C – GENERAL HEALTH SF12 ©

C7. During the past 4 weeks, how often have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)?

(Cross **ONE** box only)

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

C8. During the past 4 weeks how much did pain interfere with your normal work (both outside the home and housework)?

(Cross **ONE** box only)

- Not at all
- A little bit
- Moderately
- Quite a bit
- Extremely

C9. How much during the past 4 weeks have you felt calm and peaceful?

(Cross **ONE** box only)

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

SECTION C – GENERAL HEALTH SF12 ©

C10. How much during the past 4 weeks did you have a lot of energy?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C11. How much during the past 4 weeks have you felt downhearted and depressed?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C12. During the past 4 weeks how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

SECTION D – PAIN

Please indicate on this scale how you would rate your pain today? The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a cross (X) on the line that best indicates the rating of your pain today.

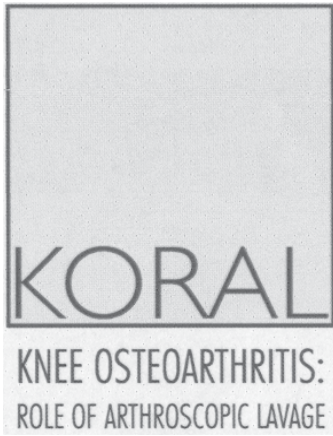


Thank you for filling in this questionnaire, please post it back to us in the envelope provided

If you would like any further information or have any queries about the study, please contact:

The KORAL Study Office in Aberdeen (Tel: 01224 554338)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, 3rd Floor, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.



STUDY No

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CONFIDENTIAL

KORAL STUDY

***ARTHROSCOPIC LAVAGE FOR TREATMENT OF
OSTEOARTHRITIS OF THE KNEE***

FOLLOW UP QUESTIONNAIRE

Thank you for helping us with research into osteoarthritis of the knee. We would be very grateful if you could complete and return this questionnaire.

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

The following questions ask about problems which may have been caused by your knee during the **past 4 weeks**.

A1. During the past 4 weeks how would you describe the pain you have from your knee?

(Cross **ONE** box only)

None	<input type="checkbox"/>
Very mild	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

A2. During the past 4 weeks have you had any trouble with washing and drying yourself (all over) because of your knee?

(Cross **ONE** box only)

No trouble at all	<input type="checkbox"/>
Very little trouble	<input type="checkbox"/>
Moderate trouble	<input type="checkbox"/>
Extreme trouble	<input type="checkbox"/>
Impossible to do	<input type="checkbox"/>

A3. During the past 4 weeks have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you tend to use).

(Cross **ONE** box only)

No trouble at all	<input type="checkbox"/>
Very little trouble	<input type="checkbox"/>
Moderate trouble	<input type="checkbox"/>
Extreme difficulty	<input type="checkbox"/>
Impossible to do	<input type="checkbox"/>

A4. During the past 4 weeks for how long have you been able to walk before the pain from your knee becomes severe? (with or without a stick).

(Cross **ONE** box only)

No pain at all, or no pain for more than 30 mins	<input type="checkbox"/>
16 to 30 mins	<input type="checkbox"/>
5 to 15 mins	<input type="checkbox"/>
Around the house only	<input type="checkbox"/>
Not at all - severe on walking	<input type="checkbox"/>

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

A5. During the past 4 weeks after a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

(Cross **ONE** box only)

- Not at all painful
- Slightly painful
- Moderately painful
- Very painful
- Unbearable

A6. During the past 4 weeks have you been limping when walking, because of your knee?

(Cross **ONE** box only)

- Rarely/never
- Sometimes or just at first
- Often, not just at first
- Most of the time
- All of the time

A7. During the past 4 weeks could you kneel down and get up again afterwards? (thinking of your knee)

(Cross **ONE** box only)

- Yes, easily
- With little difficulty
- With moderate difficulty
- With extreme difficulty
- No, impossible

A8. During the past 4 weeks have you been troubled by pain from your knee in bed at night?

(Cross **ONE** box only)

- No, never
- Only 1 or 2 nights
- Some nights
- Most nights
- Every night

SECTION A - HEALTH PROBLEMS CAUSED BY YOUR KNEE

A9. During the past 4 weeks how much has pain from your knee interfered with your usual work (including housework)?

(Cross **ONE** box only)

- Not at all
- A little bit
- Moderately
- Greatly
- Totally

A10. During the past 4 weeks have you felt that your knee might suddenly "give way" or let you down?

(Cross **ONE** box only)

- Rarely/never
- Sometimes or just at first
- Often, not just at first
- Most of the time
- All of the time

A11. During the past 4 weeks could you do the household shopping on your own? (thinking of your knee)

(Cross **ONE** box only)

- Yes, easily
- With little difficulty
- With moderate difficulty
- With extreme difficulty
- No, impossible

A12. During the past 4 weeks could you walk down a flight of stairs? (thinking of your knee)

(Cross **ONE** box only)

- Yes, easily
- With little difficulty
- With moderate difficulty
- With extreme difficulty
- No, impossible

SECTION B – DESCRIBING YOUR OWN HEALTH TODAY

The next two sections are about your general health.

By placing a cross (X) in one box in each group below, please indicate which statement best describes your own health state today. Do not X more than one box in each group.

Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Self-Care

I have no problems with self care

I have some problems washing and dressing myself

I am unable to wash myself

Usual activities (eg work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain / Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Anxiety / Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box below to the point on the scale that best indicates how good or bad your health state is today.

Your own health state today

Best imaginable health state

100

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90

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80

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10

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Worst imaginable health state

SECTION C – GENERAL HEALTH SF12 ©

The following questions ask for your views about your health **in the last 4 weeks**, how you feel and how well you are able to do your usual activities.

Answer every question by placing a cross in one box only. If you are unsure about how to answer any questions please give the best answer you can.

C1. In general, would you say your health is:

*(Cross **ONE** box only)*

Excellent

Very good

Good

Fair

Poor

C2. During a typical day does your health limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?

*(Cross **ONE** box only)*

Yes, limited a lot

Yes, limited a little

No, not limited at all

C3. During a typical day does your health limit you in climbing several flights of stairs? If so, how much?

*(Cross **ONE** box only)*

Yes, limited a lot

Yes, limited a little

No, not limited at all

SECTION C – GENERAL HEALTH SF12 ©

C4. During the past 4 weeks, how often have you accomplished less than you would have liked in your work or other regular daily activities as a result of your physical health?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C5. During the past 4 weeks, how often have you been limited in performing any kind of work or other regular daily activities as a result of your physical health?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C6. During the past 4 weeks, how often have you accomplished less than you would have liked in your work or any other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

SECTION C – GENERAL HEALTH SF12 ©

C7. During the past 4 weeks, how often have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)?

(Cross **ONE** box only)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C8. During the past 4 weeks how much did pain interfere with your normal work (both outside the home and housework)?

(Cross **ONE** box only)

Not at all

A little bit

Moderately

Quite a bit

Extremely

C9. How much during the past 4 weeks have you felt calm and peaceful?

(Cross **ONE** box only)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

SECTION C – GENERAL HEALTH SF12 ©

C10. How much during the past 4 weeks did you have a lot of energy?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C11. How much during the past 4 weeks have you felt downhearted and depressed?

*(Cross **ONE** box only)*

All of the time

Most of the time

Some of the time

A little of the time

None of the time

C12. During the past 4 weeks how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

*(Cross **ONE** box only)*

All of the time

Most of the time

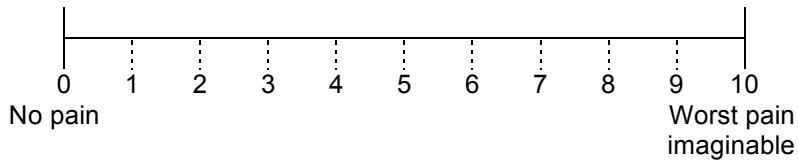
Some of the time

A little of the time

None of the time

SECTION D – PAIN

D1. Please indicate on this scale how you would rate your pain today? The best rating is marked 0 (no pain) and the worst rating is marked 10 (worst imaginable pain). Please draw a cross (X) on the line that best indicates the rating of your pain today.



D2. If you are currently being PRESCRIBED any medication to manage your pain, please list below the name(s) of the medicine(s) and include the number of times you have taken it in the last two weeks.

Name of medication	No. of times taken in the last 2 weeks

D3. Please list below the names of any NON PRESCRIBED (over the counter) medication you take for your pain and include the number of times you have taken it in the last two weeks.

Name of medication	No. of times taken in the last 2 weeks

SECTION E – YOUR FOLLOW-UP

E1. In the study you were randomised to surgery or to non-surgical management. People who were randomised to surgery either had surgery (arthroscopic lavage) or placebo surgery (a simulated arthroscopic lavage that mimics the surgical procedure).

If you had surgery on your knee as part of the KORAL study, which type of surgery do you think you had?

Surgery (arthroscopic lavage)

Placebo surgery (simulated arthroscopic lavage)

*(Cross **ONE** box only)*

Don't know

Thank you for filling in this questionnaire, please post it back to us in the envelope provided

If you would like any further information or have any queries about the study, please contact:

The KORAL Study Office in Aberdeen (Tel: 01224 554338)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, 3rd Floor, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.