Date

day / month / year

VenUS III Ultrasound

VenUS III: Ultrasound Trial - Pre-trial Screening Form (April 2006)

Centre: _____ Patient Sex: Male ☐ Female ☐

Patient's DoB: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Current compression level: High ☐ Moderate/Low ☐ None ☐

Does the patient's leg ulcer have more than 25% slough? Yes ☐ No ☐

If Yes, please consider the patient for inclusion in the VenUSII larval therapy trial, if available in your centre.

The following are exclusion criteria for the VenUSIII Ultrasound trial: Please Cross ALL that apply

		Yes
1.	Patient has been in VenUS III ultrasound trial previously	☐
2.	Patient has one or more of the contraindications to Ultrasound ***that are listed overleaf.*** *(Please indicate which by crossing the relevant box overleaf)*	☐
3.	Patient is a woman of child bearing potential, or pregnant or breastfeeding	☐
4.	Patient is currently in a trial evaluating other therapies for leg ulcers (except for 6 months post-recruitment into the VenUSII larval therapy trial)	☐
5.	Patient is allergic to ultrasound transmission gel	☐
6.	ABPI is less than 0.8 (measured within the last 3 months)	☐
7.	Patient's leg ulcer is equal to or less than $5cm^2$ in area **and** less than 6 months duration	☐
8.	Patient will not consider ultrasound therapy	☐
9.	Patient has uncontrolled diabetes (HbA_{1c} > 10% measured within the last 3 months)	☐
10.	Patient unwilling to give informed consent	☐
11.	Patient unable to give informed consent	☐
12.	Patient is under 18 years of age	☐

If you have put an 'X' in any box, this means the patient is **NOT ELIGIBLE** to enter the trial.
If this is the case please **RETURN THIS FORM** to your local research nurse.

If the patient is **ELIGIBLE** to enter the trial, please give them the **patient information sheet**.
Arrange to see them after at least 24 hours (you may wish to see them at your next scheduled appointment rather than arranging a special visit).

Please now give the patient information sheet to the patient.

Nurse's name _____ **Signature** _____

Recognised contraindications to Ultrasound treatment are (on the leg to be treated):

	Please cross relevant contraindication
• Ankle or knee prosthesis	☐
• Metal anywhere in the foot or leg (e.g. pin or plate; shrapnel)	☐
• Suspected or confirmed local cancer/metastatic disease	☐
• Suspected thrombophlebitis *(please reconsider patient for trial once this has resolved)*	☐
• Active cellulitis *(please reconsider patient for trial once this has resolved)*	☐
• Obvious ulcer infection *(please reconsider patient for trial once this has resolved)*	☐
• Other	☐

If Other please specify _____

Date Form Completed

day / month / year

VenUS III: Ultrasound Trial -Patient Record Form

BEFORE completing this form please ensure that the patient has signed the consent form indicating their willingness to take part in the trial

Date informed consent obtained day / month / year

VenUS III (Venous Ulcer Studies III - Ultrasound for venous leg ulcers)
A multicentre randomised trial, funded by the NHS Health Technology Assessment Programme
(International Standardised Randomised Controlled Trial No: 21175670 & EudraCT No. 2004-004911-51)

8393102444

Please follow the following checklist to confirm if the patient is eligible to enter the trial.

Please answer every question by placing a cross in the appropriate box.

1. Hard to heal criterion

Is the reference ulcer equal to or less than 5cm^2 in area and less than 6 months old?
(The reference ulcer is the largest ulcer in patients with more than one ulcer)

Yes	No
☐	☐

2. Arterial supply criterion

Is the ABPI equal to or greater than 0.8?

Yes	No
☐	☐

3. Consent criterion

Has the patient provided informed written consent to entering the trial?
I.e. Have they read and understood the patient information sheet and signed the patient consent form?

Yes	No
☐	☐

If any of the responses fall into the grey boxes then the patient is NOT ELIGIBLE for the trial

Ulcer history and initial assessment

The **reference leg** will be the leg with the largest ulcer.

1. Please indicate the leg being followed in the trial

Left ☐ Right ☐

2. ABPI of the reference leg ☐☐.☐☐ (e.g. 1.06 or 0.85) Date taken ☐☐ / ☐☐ / ☐☐☐☐ *day* *month* *year*

3. Total number of ulcer EPISODES on reference leg since the first episode? ☐☐

4. How long is it since the patient developed the FIRST leg ulcer? ☐☐ years ☐☐ months

The reference ulcer is identified as the largest ulcer on the leg.

5. Duration of the reference ulcer? ☐☐ years ☐☐ months

6. Duration of the oldest ulcer on the reference leg? ☐☐ years ☐☐ months

7. Mobility (please cross one box only)

Patient walks freely ☐

Patient walks with difficulty ☐

Patient is immobile ☐

8. Ankle mobility/ trial leg (please cross one box only)

Patient has full range of ankle motion ☐

Patient has reduced range of ankle motion ☐

Patient's ankle is fixed ☐

9. Patient's Height ☐☐ feet ☐☐ inches **or** ☐☐☐.☐☐ cm

10. Patient's Weight ☐☐ stone ☐☐ lbs **or** ☐☐☐.☐☐ kgs

11. Ankle circumfrence (of reference leg) ☐☐.☐☐ cm

12. On the following diagram (Page 5), please draw and label clearly all ulcers on both legs and give each one an identification code.

Label the largest ulcer R1 (if on the right leg) or L1 (if on the left leg).

If there is more than one ulcer, order them in descending order of area, i.e. largest R1, next largest R2 etc..

Please write the identification code of the **REFERENCE ULCER** (the largest ulcer on the leg) in the box below and **CIRCLE** the reference ulcer on the following diagram of the legs.

REFERENCE ULCER IDENTIFICATION CODE (e.g. R1, L1) ☐☐

Please enter the other ulcer identification codes in the boxes below.

OTHER ULCER IDENTIFICATION CODES

☐☐ ☐☐ ☐☐ ☐☐
☐☐ ☐☐ ☐☐ ☐☐
☐☐ ☐☐ ☐☐ ☐☐

13. TRACING

Using the grids provided, please trace all the ulcers on both legs.

Please confirm you have taken tracing(s) of **ALL** ulcers on the both of the legs

Yes ☐ No ☐

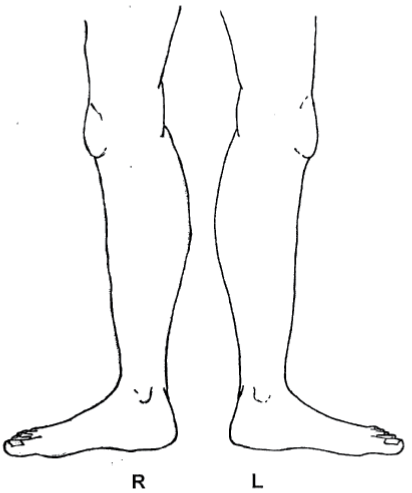
Please attach the tracings to the back of this form.

14. PHOTOGRAPH

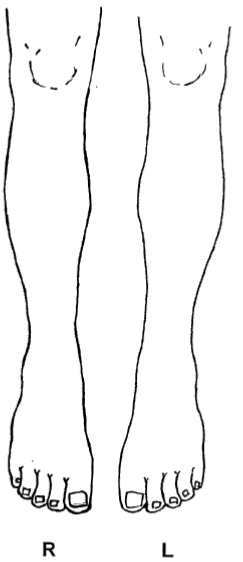
Using the digital camera, please take a photograph of the **reference ulcer**.

Please confirm you have taken a digital photograph of the **reference ulcer**.

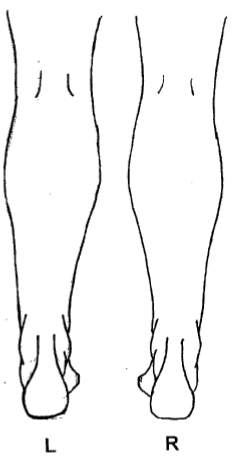
Yes ☐ No ☐



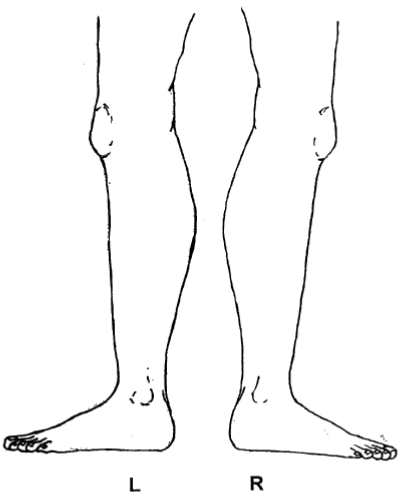
MEDIAL



FRONT



BACK



LATERAL

15. Please ask about any pain they may have experienced from the leg ulcer(s) on the **reference leg** in the past 24 hours.

Read the instructions out to the patient on how to complete the pain analogue scale before asking the question.

Instructions for completing the scale:
Place a cross on the scale below to indicate how intense the pain you have experienced is, ranging from 'no pain' to the 'worst pain imaginable'.

Question:
What is the worst pain you have had in your leg ulcer in the last 24 hours?

Office Use Only

16. Documentation

Has the patient completed the baseline questionnaire?

Yes	No
☐	☐

If **yes**, please now complete the following randomisation section and call the randomisation service in order to allocate the patient their treatment.

If **no**, please ask them to do so, and then complete the following randomisation section and call the randomisation service in order to allocate the patient their treatment.

Please complete the following section and call the randomisation service to randomise the patient.

Date

day / month / year

VenUS III: Ultrasound Trial Randomisation Form

Patient Details

Patient's Full Name

Patient's Address

Patient's Postcode

Patient's Telephone Nos. **Day** **Eve**

Patient's Date of Birth (day / month / year)

Patient's Gender Male Female

Trial Centre:

- Altnagelvin
- Bolton
- Bradford
- Cumbria
- Doncaster
- Harrogate
- Other
- Hull
- Leeds Acute
- Leeds Community
- Scarborough
- York

Size of ulcer: Equal to or less than 5cm^2 More than 5cm^2

Ulcer duration: Equal to or less than 6 months More than 6 months

Type of ulcer: Venous ulcer? Yes No

Compression level:

Is this patient being treated with high compression? (e.g. 2 or 3 or 4 layer high compression bandaging) Yes No

Once these questions are complete, please call the randomisation service on 0800 0566682 between 08:30 and 17:30 Monday to Friday, and then complete the allocation details on the following page according to the details given by the telephonist.

Allocation Details

After randomisation, please complete the details below.

Please enter the Patient's Trial Number: ☐☐ - ☐☐☐☐

The patient has been assigned to:

Ultrasound ☐

No Ultrasound ☐

Nurses Name: _____

Nurses signature: _____

Please attach the patient's ulcer tracing(s) to the back of this form and return it to your local research nurse.

THE UNIVERSITY of York

CONFIDENTIAL

VenUS III Ultrasound Study

Baseline Questionnaire (May 2006)

Participant ID Number [ ][ ] - [ ][ ][ ][ ]

This unique number will be allocated to the patient when the nurse telephones the randomisation service.

Nurse: Please enter the number in the boxes above after you have been given it by the randomisation service.

Date [ ][ ] / [ ][ ] / [2][0][ ][ ]

VenUS III
Ultrasound

VenUS III (Venous Ulcer Studies III - Ultrasound for venous leg ulcers)
A multicentre randomised trial, funded by the NHS Health Technology Assessment Programme
(International Standardised Randomised Controlled Trial No: 21175670 & EudraCT No. 2004-004911-51)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study.

We would like to find out a little about your health and how your leg ulcer might affect your life.

Please answer **ALL** the questions. Although some of the questions may not seem relevant to yourself, they do give us valuable information about your leg ulcer.

If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example, in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car? **Yes** ☒

No ☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question, if you are asked 'How happy are you today?' where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy nor unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

1 **2** **(3)** **4** **5**

PLEASE USE A BLACK OR BLUE PEN FOR ALL OF THE QUESTIONS.

Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

This section asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross 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 or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. 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 ☐

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

Answer every question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate actvities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the **past 4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please 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
☐	☐	☐	☐	☐

5. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of your physical health** ?
(please 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
☐	☐	☐	☐	☐

6. During the **past 4 weeks**, how much of the time 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) ?
(please 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
☐	☐	☐	☐	☐

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

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

9. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt calm and peaceful ?
(please 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
☐	☐	☐	☐	☐

10. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** did you have a lot of energy ?
(please 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
☐	☐	☐	☐	☐

11. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt downhearted and depressed ?
(please 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
☐	☐	☐	☐	☐

12. 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.) ?
(please 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
☐	☐	☐	☐	☐

Please enter today's date ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

In order to accurately measure the cost of different leg ulcer treatments, we would like to know the number of times you have seen a health professional (e.g. doctor or nurse) **not** as part of this study.

1. In the **last 3 months** have you seen a doctor at your **doctor's surgery** OR seen a **doctor at home** for any reason relating to your health ?

Yes ☐
No ☐

If **Yes**, how many times...

have you seen a doctor at the surgery ? ☐☐

have you been visited at home by a doctor ? ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐
No ☐

If **Yes**, how many times ? ☐☐

2. In the **last 3 months** have you seen a nurse at your **doctor's surgery** OR seen a **nurse at home** for any reason relating to your health ?

Yes ☐
No ☐

If **Yes**, how many times...

have you seen a nurse at the surgery ? ☐☐

have you been visited at home by a nurse ? ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐
No ☐

If **Yes**, how many times ? ☐☐

3. In the **last 3 months** have you **been to hospital as an outpatient** for any reason relating to your health ?

Yes ☐

No ☐

If **Yes**, how many times... ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐

No ☐

If **Yes**, how many times... ☐☐

4. In the **last 3 months** which of the following have helped you around the house, to do the shopping etc. ?
(place a cross in the box for all of those who have helped and then enter the number of hours per week they have helped you. If you have not needed any help put a cross in the 'I have not needed any help' box)

I have not needed any help ☐

Home help ☐ approximately how many hours per week ☐☐☐

Relative ☐ approximately how many hours per week ☐☐☐

Friend/ neighbour ☐ approximately how many hours per week ☐☐☐

Other ☐ approximately how many hours per week ☐☐☐

If you have selected 'Other' please state relationship in box below)

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your ulcer, the study, or this questionnaire, please write them below.

Patient Trial Number ☐☐ - ☐☐☐☐

VenUS III: Ultrasound Trial

ULTRASOUND TREATMENT LOG BOOKLET (April 2006)

To be used for all patients allocated to Ultrasound DURING their 12 weeks of Ultrasound, after which the Dressing Log Booklet should be used

Booklet Number

☐☐

- Please complete a page in the Ultrasound Treatment Log Booklet at each visit to the patient and complete the following trial documentation at the appropriate times.
- When the Reference ulcer has healed please complete an **Ulcer Healed Form**.
- When the last ulcer has healed (i.e. the patient is ulcer free) please complete an **Ulcer Healed Form**.
- If the only ulcer on the leg has healed please also complete a **Change of Circumstances Form**.
- If there are unhealed ulcers on the leg, continue to complete the Dressing Log Booklet until all ulcers have healed - when this occurs please complete a **Change of Circumstances Form**.
- If the reference ulcer is not healed in 12 months please complete a **Change of Circumstances Form**.

Please report any patient event observed today and complete the relevant form. Please ensure you adhere to your employing Trust's adverse event procedure.

A list of possible adverse events is listed below. This is NOT an exhaustive list. If you suspect an event is serious please contact the trial manager. We would rather you err on the side of caution and report an adverse event.

Please complete a Non-Serious Adverse Event (NSAE) form for any of the following:

Pressure damage

Infection

Skin damage surrounding ulcer

New ulcer

Ulcer deterioration (Please also complete a 'Change of Circumstances Form')

Patient had experienced an adverse reaction to the ultrasound treatment or contact gel (Please also complete a 'Change of Circumstances Form')

Please complete a Serious Adverse Event (SAE) form for any of the following:

Patient has died (Please also complete a 'Change of Circumstances Form')

Patient has been admitted to hospital for more than 24 hours (Please also complete a 'Change of Circumstances Form')

Limb compromise

Life - threatening event

Persistent or significant disability/incapacity

Patient is a newly diagnosed diabetic

Please note this is not an exhaustive list, if you suspect an event is serious, please contact the Trial Manager at the York Trials Unit. We would rather you erred on the side of caution and reported an event to us.

If the patient has had any change in treatment (deviating from the protocol) please complete a 'Change of Circumstances Form'

Data collection checklist

For each visit, please complete a new page in this booklet recording the treatment applied.

Every 4 weeks from the first trial treatment (first day of treatment equals Day 0), please take a **digital photograph** of the **REFERENCE ULCER**.

Every 4 weeks from the first trial treatment (i.e. at the same time as taking the photograph of the reference ulcer), please take **tracings** of **ALL** the leg ulcers the patient has.

These key data collection times can also be seen in the "**Record of data collected for a recruited patient**" form which should be kept in the front of the patient's records.

ULTRASOUND TREATMENT LOG
PLEASE COMPLETE THIS FORM EVERY TIME A PATIENT IS SEEN BY A NURSE FOR LEG ULCER TREATMENT IN THE FIRST 12 WEEKS AFTER TRIAL ENTRY

Date of Visit ☐☐ / ☐☐ / ☐☐
day *month* *year*

Location (place a cross in one box only)

Home	☐	GP Surgery	☐
Leg ulcer clinic	☐	Leg ulcer club	☐
Nursing Home	☐	Other (specify below)	☐

_____

Have you applied ultrasound today? (NB: once weekly) Yes ☐ No ☐

If yes, how long was it applied for? ☐☐ mins

If yes,what is the machine number? ☐☐

If yes, please sign to confirm you have carried out the above treatment

_____ _____
(Please sign here) *(Please print your name here)*

Knitted viscose dressing (KVD) applied Yes ☐ No ☐

Please report any change to the primary dressings and state reasons why below (please put name of primary dressing/wound contact layer/topical agent applied apart from a KVD) AND complete a 'Change of Circumstances' Form

_____

Compression bandages applied (please cross one box only):

4 layer high compression	☐	3 layer reduced compression	☐
3 layer high compression	☐	Low compression	☐
2 layer high compression	☐	No compression	☐
Short Stretch	☐		

Please report any change of compression therapy and state reason why below AND complete a 'Change of Circumstances' form.

_____

Has there been an **adverse event** since your last visit? Yes ☐ No ☐

If **yes**, please complete the relevant form described at the beginning of this booklet

Patient Trial Number ☐☐ - ☐☐☐☐

VenUS III: Ultrasound Trial

DRESSING LOG BOOKLET (April 2006)

To be used for all patients allocated to Standard Care and patients allocated to Ultrasound AFTER their 12 weeks of Ultrasound

Booklet Number

☐☐

- Please complete a page in the Dressing Log Booklet at each visit to the patient and complete the following trial documentation at the appropriate times.
- When the Reference ulcer has healed please complete an **Ulcer Healed Form**.
- When the last ulcer has healed (i.e. the patient is ulcer free) please complete an **Ulcer Healed Form**.
- If the only ulcer on the leg has healed please also complete a **Change of Circumstances Form**.
- If there are unhealed ulcers on the leg, continue to complete the Dressing Log Booklet until all ulcers have healed - when this occurs please complete a **Change of Circumstances Form**.
- If the reference ulcer is not healed in 12 months please complete a **Change of Circumstances Form**.

Please report any patient event observed today and complete the relevant form. Please ensure you adhere to your employing Trust's adverse event procedure.

A list of possible adverse events is listed below. This is NOT an exhaustive list. If you suspect an event is serious please contact the trial manager. We would rather you err on the side of caution and report an adverse event.

Please complete a Non-Serious Adverse Event (NSAE) form for any of the following:

Pressure damage

Infection

Skin damage surrounding ulcer

New ulcer

Ulcer deterioration (Please also complete a 'Change of Circumstances Form')

Patient had experienced an adverse reaction to the ultrasound treatment or contact gel (Please also complete a 'Change of Circumstances Form')

Please complete a Serious Adverse Event (SAE) form for any of the following:

Patient has died (Please also complete a 'Change of Circumstances Form')

Patient has been admitted to hospital for more than 24 hours (Please also complete a 'Change of Circumstances Form')

Limb compromise

Life - threatening event

Persistent or significant disability/incapacity

Patient is a newly diagnosed diabetic

Please note this is not an exhaustive list, if you suspect an event is serious, please contact the Trial Manager at the York Trials Unit. We would rather you erred on the side of caution and reported an event to us.

If the patient has had any change in treatment (deviating from the protocol) please complete a 'Change of Circumstances Form'

Data collection checklist

For each visit, please complete a new page in this booklet recording the treatment applied.

Every 4 weeks from the first trial treatment (first day of treatment equals Day 0), please take a **digital photograph** of the **REFERENCE ULCER**.

Every 4 weeks from the first trial treatment (i.e. at the same time as taking the photograph of the reference ulcer), please take **tracings** of **ALL** the leg ulcers the patient has.

These key data collection times can also be seen in the "**Record of data collected for a recruited patient**" form which should be kept in the front of the patient's records.

DRESSING LOG
PLEASE COMPLETE THIS FORM EVERY TIME A PATIENT IS SEEN BY A NURSE FOR LEG ULCER TREATMENT

Date of Visit ☐☐ / ☐☐ / ☐☐
day *month* *year*

Location (place a cross in one box only)

Home	☐	GP Surgery	☐
Leg ulcer clinic	☐	Leg ulcer club	☐
Nursing Home	☐	Other (specify below)	☐

Knitted viscose dressing (KVD) applied Yes ☐ No ☐

Please report any change to the primary dressings and state reasons why below (please put name of primary dressing/wound contact layer/topical agent applied apart from a KVD) AND complete a 'Change of Circumstances' Form

Compression bandages applied (please cross one box only):

4 layer high compression	☐	3 layer reduced compression	☐
3 layer high compression	☐	Low compression	☐
2 layer high compression	☐	No compression	☐
Short Stretch	☐		

Please report any change of compression therapy and state reason why below AND complete a 'Change of Circumstances' form.

Has there been an **adverse event** since your last visit? Yes ☐ No ☐

If **yes**, please complete the relevant form described at the beginning of this booklet

Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Patient Trial Number: ☐☐ - ☐☐☐☐

VenUS III: Ultrasound Trial - Change of Circumstances Form - Version 2 (March 2006)

Please complete this form if there are any changes in the circumstances of the VenUS III participant.

Reason for change in circumstance:

Please read the following and write the number of the MAIN reason in the box at the end of this form.

1. **The patient no longer wishes to:**

(please tick all that apply)

   a) **Have the trial treatment** ☐
   NB: this is not the same as change of treatment due to clinical needs - see options 5, 6 or 7

   b) **Complete their postal questionnaires** ☐

   c) **Have data collected by the nurse about their ulcer(s)** ☐
   e.g. ulcer tracings/ photos/dressing log booklets

2. **Patient has experienced an Adverse Event** *(Please also complete either a 'Non-serious Adverse Events Form' or a 'Serious Adverse Events Form' - refer to inside cover of dressing log booklet for guidelines as to which is appropriate. If still unsure, please telephone York Trials Unit)*

3. **The patient is ulcer free** *(Please also complete an 'Ulcer Healed Form')*

4. **Patient has been in the trial for 12 months and is therefore being withdrawn** *(May still have ulcers on their legs)*

5. **Patient's ulcer has increased in area for two consecutive weeks and therefore treatment has been changed** *(Please provide details in treatment/ dressing log)*

6. **Patient's ulcer has deteriorated and therefore treatment has been changed** *(Please provide details in treatment/ dressing log)*

7. **Treatment has changed due to a reason other than options 5 or 6** *(Please provide details in treatment/ dressing log)*

8. **Patient is lost to follow-up**

9. **Patient has died** *(Please also complete a 'Serious Adverse Events Form')*

10. **Other reason** *(please state)* ☐

The **MAIN** reason for the change is option number ☐☐ (Please write option number in box)

Please give more details, if applicable: ☐

Is the patient completely ulcer free? ☐ **Yes** ☐ **No**

If NO, please take a tracing of all unhealed ulcers and a digital photo of the reference ulcer if it is unhealed

Please confirm that you have traced all unhealed ulcers (and photographed reference ulcer if unhealed) and attached the tracings to the back of this form ☐ **Yes** ☐ **No**

Please send this form and all patient documentation to your local research nurse

Date form completed

☐☐ / ☐☐ / ☐☐

day *month* *year*

VenUS III Ultrasound

VenUS III: Ultrasound Trial - Ulcer Healed Form

Patient Trial Number ☐☐ - ☐☐☐☐

PLEASE complete this form when:

a) The Reference Ulcer has healed and / or

b) The last ulcer has healed (i.e. the patient is ulcer free)

1) Has the **Reference ulcer** healed today ?
(i.e. the largest ulcer at the baseline visit) Yes ☐ No ☐

If yes, please take a DIGITAL PHOTOGRAPH of the reference ulcer and confirm that you have done so below.

Please confirm you have taken a digital photograph of the healed reference ulcer

Yes ☐ No ☐

Please make sure that you have included on the colour target card, the:

- date,
- patient trial number,
- ulcer ID (e.g. R1, R2 etc).

Send the compact flash card to your local research nurse for storage.

2) Has the last ulcer healed today?
(i.e. the patient is ulcer free) Yes ☐ No ☐

If no, please continue to complete the dressing log until the patient is free from ulcers on both legs. When the patient is ulcer free on both legs, please complete another **Ulcer Healed Form**

If yes, please complete the **Change in Circumstances Form** to inform us of trial completion

NOTE: You do not need to inform us of the dates of healing of any non-reference ulcers until the patient has healed **all** their leg ulcers (i.e. - they are ulcer free)

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VenUS III Ultrasound Study

Three Month Questionnaire

Participant ID Number [ ][ ] - [ ][ ][ ][ ]

This unique number will be allocated to the patient when the nurse telephones the randomisation service.

Nurse: Please enter the number in the boxes above after you have been given it by the randomisation service.

Date [ ][ ] / [ ][ ] / [2][0][ ][ ]

VenUS III Ultrasound

VenUS III (Venous Ulcer Studies III - Ultrasound for venous leg ulcers)
A multicentre randomised trial, funded by the NHS Health Technology Assessment Programme
(International Standardised Randomised Controlled Trial No: 21175670 & EudraCT No. 2004-004911-51)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study.

We would like to find out a little about your health and how your leg ulcer might affect your life.

Please answer **ALL** the questions. Although some of the questions may not seem relevant to yourself, they do give us valuable information about your leg ulcer.

If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example, in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car? **Yes** ☒

No ☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question, if you are asked 'How happy are you today?' where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy nor unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

1 **2** **(3)** **4** **5**

PLEASE USE A BLACK OR BLUE PEN FOR ALL OF THE QUESTIONS.

Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

This section asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross 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 or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. 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 ☐

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

Answer every question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate actvities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the **past 4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please 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
☐	☐	☐	☐	☐

5. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of your physical health** ?
(please 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
☐	☐	☐	☐	☐

6. During the **past 4 weeks**, how much of the time 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) ?
(please 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
☐	☐	☐	☐	☐

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

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

9. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt calm and peaceful ?
(please 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
☐	☐	☐	☐	☐

10. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** did you have a lot of energy ?
(please 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
☐	☐	☐	☐	☐

11. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes closest to the way you have been feeling. How much during the **past 4 weeks** have you felt downhearted and depressed ?
(please 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
☐	☐	☐	☐	☐

12. 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.) ?
(please 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
☐	☐	☐	☐	☐

Please enter today's date ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

In order to accurately measure the cost of different leg ulcer treatments, we would like to know the number of times you have seen a health professional (e.g. doctor or nurse) **not** as part of this study.

1. In the **past 4 weeks** have you seen a doctor at your **doctor's surgery** OR seen a **doctor at home** for any reason relating to your health ?

Yes ☐
No ☐

If **Yes**, how many times...

have you seen a doctor at the surgery ? ☐☐

have you been visited at home by a doctor ? ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐
No ☐

If **Yes**, how many times ? ☐☐

2. In the **past 4 weeks** have you seen a nurse at your **doctor's surgery** OR seen a **nurse at home** for any reason relating to your health ?

Yes ☐
No ☐

If **Yes**, how many times...

have you seen a nurse at the surgery ? ☐☐

have you been visited at home by a nurse ? ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐
No ☐

If **Yes**, how many times ? ☐☐

3. In the **past 4 weeks** have you **been to hospital as an outpatient** for any reason relating to your health ?

Yes ☐

No ☐

If **Yes**, how many times... ☐☐

Were any of these visits because of your leg ulcer ?

Yes ☐

No ☐

If **Yes**, how many times... ☐☐

4. In the **past 4 weeks** which of the following have helped you around the house, to do the shopping etc. ?
(place a cross in the box for all of those who have helped and then enter the number of hours per week they have helped you. If you have not needed any help put a cross in the 'I have not needed any help' box)

I have not needed any help ☐

Home help ☐ approximately how many hours per week ☐☐☐

Relative ☐ approximately how many hours per week ☐☐☐

Friend/ neighbour ☐ approximately how many hours per week ☐☐☐

Other ☐ approximately how many hours per week ☐☐☐

If you have selected 'Other' please state relationship in box below)

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your ulcer, the study, or this questionnaire, please write them below.

VenUS III: Ultrasound Trial

NON-SERIOUS ADVERSE EVENT FORM

Patient concerned (Trial number) ☐☐ – ☐☐☐☐

Name of nurse reporting event

Name of Local Research Nurse (if different from above)

Date of event ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Details of event

Action taken

Do you think the event is related to the trial treatment (contact gel or ultrasound therapy)?
(please tick only ONE box)

Unrelated	Unlikely to be related	Possibly related	Probably related	Definitely related	Not able to assess if related
☐	☐	☐	☐	☐	☐

If the AE has resulted in any of the following you must complete a Serious Adverse Event (SAE) form instead:

- death
- a life-threatening risk (that is an immediate risk of death)
- hospitalisation of patient
- persistent or significant disability / incapacity
- other medically important condition

Possible SAEs in the VenUS III trial. Please note this is not an exhaustive list. If you suspect an event is serious, please contact the Trial Manager at the York Trials Unit. We would rather you erred on the side of caution and reported an event to us.

VenUS III: Ultrasound Trial

REVIEW OF NON-SERIOUS ADVERSE EVENT

Patient concerned (Trial ID number) ☐☐ – ☐☐☐☐

How and when notification of the event was made

Date of review ☐☐ / ☐☐ / ☐☐☐☐
Day *Month* *Year*

Action taken

Signature of reviewer

For York use only

Date reviewed by Trial Management Group ☐☐ / ☐☐ / ☐☐☐☐
Day *Month* *Year*

VenUS III: Ultrasound trial

SERIOUS ADVERSE EVENT FORM

Patient Trial Number ☐☐ - ☐☐☐☐

Date of birth ☐☐ day ☐☐ month ☐☐ year Male ☐ Female ☐

Date of onset of event ☐☐ day ☐☐ month ☐☐ year

Description of event:

Classification of SAE: (tick all that apply)
Death ☐ | Life or limb threatening event ☐ | Hospitalisation required /prolonged ☐
Persistent or significant disability/incapacity ☐ | Other medically important condition ☐

PLEASE OBTAIN COPIES OF ANY AVAILABLE SUPPORTING DOCUMENTS RELATING TO THE EVENT FOR FORWARDING TO THE VENUS III TRIAL MANAGER.

Please state outcome of event at time of this report (tick one box only)

		Date recovered / died
Recovered fully	☐	☐☐ day ☐☐ month ☐☐☐☐ year
Recovered partially	☐	☐☐ day ☐☐ month ☐☐☐☐ year
Died	☐	☐☐ day ☐☐ month ☐☐☐☐ year
Ongoing	☐	

Relationship of event to treatment ***(tick one box only)***

Unrelated	Unlikely to be related	Possibly related	Probably related	Definitely related	Not able to assess if related
☐	☐	☐	☐	☐	☐

York Trials Unit must be notified of any serious adverse event by telephone (01904 321 306) within 24 hours of onset of the event.

Post or fax the top copy of this form and any available supporting documents to Dr Jude Watson, Trial Manager, Department of Health Sciences (Area 4), Seebohm Rowntree Building, University of York, Heslington, YORK YO10 5DD, within 48 hours of onset (Fax no: 01904 321387).

Please note that we may need to inform your Local Research Ethics Committee of this event.

Final date of resolution if known: ☐☐ day ☐☐ month ☐☐☐☐ year

Outcome if known: Recovered fully ☐ Recovered partially ☐

Possible SAEs in the VenUS III trial:
Patient has died; **Limb compromise** (limb requires revascularisation or amputation)**; Newly diagnosed diabetic** (patient diagnosed as diabetic by GP during course of trial)**; Patient hospitalised for longer than 24 hours for any reason**.
**Please note this is not an exhaustive list, if you suspect an event is serious or are unsure, please contact the Trial Manager at the York Trials Unit. We would rather you erred on the side of caution and reported an event to us. **

Local Researcher's name (block capitals) _____

Local Researcher's signature _____

1 copy to be sent to the Trial manager at the York Trials Unit, 1 copy to be kept in patient's notes and 1 copy to be kept by Local Research Nurse.

VenUS III: Ultrasound Trial

REVIEW OF SERIOUS ADVERSE EVENT

Patient concerned (Trial ID number) ☐☐ - ☐☐☐☐

How and when notification of the event was made

Date of review ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Action taken

Signature of reviewer

For York Use Only

Date reviewed by TSC And DMEC ☐☐ / ☐☐ / ☐☐☐☐