THE UNIVERSITY of York

**CONFIDENTIAL**

# VenUS IV Leg ulcer study

## Baseline 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.***

Today's Date [ ][ ] / [ ][ ] / [2][0][ ][ ]
*Day* *Month* *Year*

**VenUS IV (Venous Ulcer Study IV - Compression hosiery for venous leg ulcers)**
A multicentre randomised trial, funded by the NIHR Health Technology Assessment Programme
(International Standardised Randomised Controlled Trial No:ISRCTN49373072)

## 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.

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

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** ☐

**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.**

**Section 1**

**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 ☐

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**Section 2**

**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)*

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

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 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

**Section 3**

**This section asks you some questions specifically about your legs**

**Below are some questions about your views about your legs.** Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

**1.** During the past 4 weeks, how often have you had any of the following leg problems? (*For each question, please place a cross in one box ONLY*)

| | Every day | Several times a week | About once a week | Less than once a week | Never |
|---|---|---|---|---|---|
| a. Heavy legs | ☐ | ☐ | ☐ | ☐ | ☐ |
| b Aching legs | ☐ | ☐ | ☐ | ☐ | ☐ |
| c. Swelling | ☐ | ☐ | ☐ | ☐ | ☐ |
| d. Night cramps | ☐ | ☐ | ☐ | ☐ | ☐ |
| e. Heat or burning sensation | ☐ | ☐ | ☐ | ☐ | ☐ |
| f. Restless legs | ☐ | ☐ | ☐ | ☐ | ☐ |
| g. Throbbing | ☐ | ☐ | ☐ | ☐ | ☐ |
| h. Itching | ☐ | ☐ | ☐ | ☐ | ☐ |
| i. Tingling sensation (e.g. pins and needles) | ☐ | ☐ | ☐ | ☐ | ☐ |

2. At what time of day is your **leg problem** most intense?
*(Please place a cross in one box ONLY)*

- On waking ☐
- At mid-day ☐
- At the end of the day ☐
- During the night ☐
- At any time of day ☐
- Never ☐

3. Compared to one year ago, how would you rate your **leg problem** in general now?
*(Please place a cross in one box ONLY)*

- Much better now than one year ago ☐
- Somewhat better now than one year ago ☐
- About the same now as one year ago ☐
- Somewhat worse now than one year ago ☐
- Much worse now than one year ago ☐
- I did not have any leg problem last year ☐

4. The following items are about activities that you might do in a typical day. Does your leg problem now limit you in these activities? If so, how much?
*(Please place a cross in one box ONLY)*

| | I do not work | YES, limited a lot | YES, limited a little | NO, not limited at all |
|---|---|---|---|---|
| a. Daily activities at work | ☐ | ☐ | ☐ | ☐ |
| b. Daily activities at home (e.g. house-work, ironing, doing odd jobs/repairs around the house, gardening etc) | | ☐ | ☐ | ☐ |
| c. Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc.) | | ☐ | ☐ | ☐ |
| d. Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theatre, travelling, etc.) | | ☐ | ☐ | ☐ |

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?
*(For each question, please place a cross in either the YES or NO box)*

| | YES | NO |
|---|---|---|
| a. Cut down the **amount of time** you spent on work or other activities | ☐ | ☐ |
| b. **Accomplished less** than you would like | ☐ | ☐ |
| c. Were limited in the **kind** of work or other activites | ☐ | ☐ |
| d. Had **difficulty** performing the work or other activities (for example, it took extra effort) | ☐ | ☐ |

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbours or groups?
*(Please place a cross in one box ONLY)*

Not at all ☐

Slightly ☐

Moderately ☐

Quite a bit ☐

Extremely ☐

7. How much leg pain have you had during the past 4 weeks?
*(Please place a cross in one box ONLY)*

None ☐

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your **leg problem**. 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:
(*Please place a cross in one box ONLY*)

| | **All of the Time** | **Most of the Time** | **A Good Bit of the Time** | **Some of the Time** | **A Little of the Time** | **None of the Time** |
|---|---|---|---|---|---|---|
| a. Have you felt concerned about the appearance of your leg(s)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| b. Have you felt irritable? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| c. Have you felt a burden to your family or friends? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| d. Have you been worried about bumping into things? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| e. Has the appearance of your leg(s) influenced your choice of clothing? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**Section 4**
**We would now like to ask you about the pain related to your leg ulcer(s)**

**Instructions for completing the scale:**
Place a cross in one of the boxes below to indicate the intensity of pain from your ulcer(s) over the last 24 hours, ranging from no pain to the worst pain imaginable.

1. **How intense has the pain from your leg ulcer(s) been over the past 24 hours?**

| 0 | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 | 65 | 70 | 75 | 80 | 85 | 90 | 95 | 100 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**No Pain** … **Worst pain imaginable**

☐☐☐ (For office use only)

**Instructions for completing this question:**
Place a cross in the box which best describes the intensity of pain from your ulcer(s) over the last 24 hours, ranging from no pain to very severe pain.

2. **How intense has the pain from your leg ulcer(s) been over the past 24 hours?**

| No pain | Very mild pain | Mild pain | Severe pain | Very severe pain |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

**Section 5. 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 (i.e. doctor or nurse).** If the health care you received was related to your leg ulcers, record this in the 'leg ulcer' column. If the health care was for any other reason, enter this in the 'other' column. Please answer every question, even if the answer is "0".

Please fill in both boxes, for example: if seen three times | 0 | 3 |

If seen 0 times | 0 | 0 |

**Care from the NHS**

1. In the last 3 months how many times have you consulted with any of the following NHS health care professionals?

| | **Because of leg ulcer** | **Other reason** |
|---|---|---|
| General Practitioner (GP) at doctor's surgery *(please record the number of times in the boxes)* | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| General Practitioner (GP) in your home (please record the number of times in the boxes) | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |

| | Because of leg ulcer | Other reason |
|---|---|---|
| A **NURSE** at your doctor's surgery *(please record the number of times in the boxes)* | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| A **NURSE** in your home *(please record the number of times in the boxes)* | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| A **DOCTOR** in a hospital out-patient clinic or other location *(please record the number of times in the boxes)* | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| A **NURSE** in a hospital out-patient clinic or other location *(please record the number of times in the boxes)* | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |

**2.** In the last **3 months** how many times have you:

| | Because of leg ulcer | Other reason |
|---|---|---|
| Been admitted to hospital **without** staying overnight (i.e. for a minor procedure or day surgery)? | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| Been admitted to hospital as an in-patient (i.e. stayed for 1 or more nights)? | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |
| If, over the last 3 months, you have been a **hospital in-patient**, please record how many nights you stayed in hospital. If you have stayed in hospital more than once please add the nights you stayed for each visit together and record the total. | ☐☐ *If none enter '00'* | ☐☐ *If none enter '00'* |

## THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

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