

**Date Form Completed**

		/			/	2	0		
<i>day</i>			<i>month</i>			<i>year</i>			

Participant ID Number

Nurse Code  -  -

*First three letters of SURNAME*      *day of birth*      *month of birth*  
 e.g. S M I - 2 3 - 0 2

## VenUS IV Compression Hosiery 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   /   / 2 0

*day*      *month*      *year*

Is this patient diabetic?     Yes     No

If yes, please provide HbA1c (glycated haemoglobin) below:

HbA1c   .  %      Date of measurement   /   / 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 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. Arterial supply criterion**

Yes

No

Is the ABPI equal to or greater than 0.8 and less than 1.2?

**2. Consent criterion**

Yes

No

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?*

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 is the leg with the largest ulcer.

1. Please indicate the leg on which the **reference ulcer** is located (**this is called the reference leg**) Left  Right
2. ABPI of the reference leg  .  Date taken  /  /    
(e.g. 1.06 or 0.85) 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 their **FIRST** leg ulcer?  years  months
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 of reference 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 circumference (of reference leg)  .  cm

12. On the following diagram over the page, 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 eligible ulcer) in the box below and **CIRCLE** the reference ulcer on the following diagram of the legs.

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

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

**OTHER ULCER IDENTIFICATION CODES (BOTH LEGS)**


The leg with the reference ulcer on will be termed the **REFERENCE LEG** during the trial.

### 13. TRACING

Using the grids provided, please trace all the ulcers on the **REFERENCE LEG**.

Please confirm you have taken tracings of **ALL** ulcers on the reference leg.

Yes  No

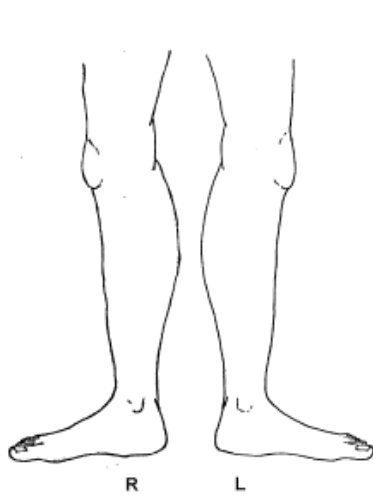
Please attach the tracings to the back of this form.

### 14. PHOTOGRAPH

Please take a photograph of the reference ulcer **AND** the reference leg.

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

Yes  No



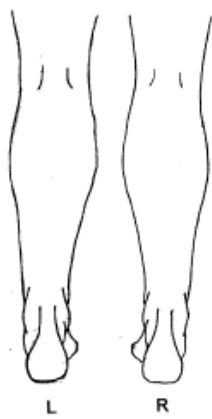
R L

MEDIAL



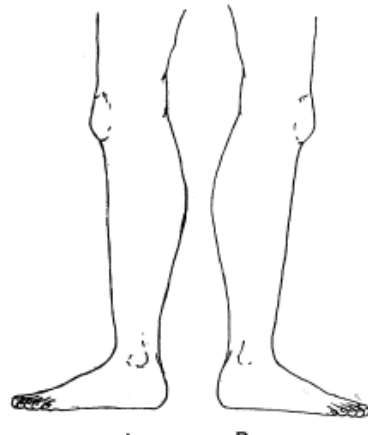
R L

FRONT



L R

BACK



L R

LATERAL

**15. Please inform the patient of the following:**

In this trial, you will be treated with either compression hosiery or compression bandaging. The local nurses and doctors have no influence over the treatment you will receive, choice will be determined randomly e.g. like tossing a coin, at the University of York.

Before we find out which treatment you will receive we would like to know if you have a particular preference for any one of the trial treatments; expressing a preference will not affect the treatment you will receive.

Please ask the patient the following question: If you had a completely free choice, which treatment would you prefer; compression hosiery or compression bandaging or do you have no preference?

(PLEASE PLACE A CROSS IN ONE BOX ONLY)

Compression hosiery (stockings)

4-layer compression bandaging

No preference

**16. What treatment(s) is this patient currently receiving for their reference leg ulcer?**

4-layer compression bandaging

Short stretch bandaging

Compression hosiery

Other compression bandaging

Not receiving compression

Other treatment

If 'Other treatment' please specify

**17. Documentation**

Has the patient completed the baseline questionnaire? Yes  No

If yes, please now complete the following randomisation section overleaf and then 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 overleaf and then call the randomisation service to randomise the patient**

Date

		/			/	2	0		
day			month			year			

Nurse Code

			-			-		
First three letters of SURNAME				day of birth			month of birth	
e.g. S M I - 2 3 - 0 2								

## VenUS IV: Compression Hosiery Trial Randomisation Form

### PATIENT DETAILS

Title (i.e. Mr, Mrs, etc)  Forename

Surname

Address

Postcode

Telephone Nos. Day  Eve

*If patient uses also record* Mobile  Email

Patient's Date of Birth  /  /   
day month year

Patient's Gender Male  Female

Trial Centre:

Size of ulcer: Equal to or less than 5cm<sup>2</sup>  More than 5cm<sup>2</sup>

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

Name of Patient's GP

Name of Surgery

Address of Surgery

Postcode

Once these questions are complete, please call the randomisation service on [REDACTED] between 09:00 and 17:00 Monday to Friday, and then complete the allocation details on the following page according to the details given by the telephonist.

OR randomisation can be done online via [REDACTED]

## Allocation Details

After randomisation, please complete the details below.

ENTER THE PARTICIPANT'S ID NUMBER ONTO THE FRONT OF THIS QUESTIONNAIRE AND ALSO THE PARTICIPANT'S BASELINE QUESTIONNAIRE IN THE SECTION LABELLED "PARTICIPANT ID NUMBER".

The patient has been assigned to:

Compression hosiery

4-layer bandaging

Nurse's Name: \_\_\_\_\_

Nurse's signature: \_\_\_\_\_

PLEASE SEND TO YORK TRIALS UNIT IN 3 SEPARATE ENVELOPES:

1. PATIENT RECORD FORM, BASELINE QUESTIONNAIRE AND ULCER TRACING
2. RANDOMISATION FORM
3. CONSENT FORM