Patient Information Sheet

THE UNIVERSITY of York

VenUS IV Leg ulcer study: Patient Information sheet

Please read this document carefully.

We would like to invite you to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Feel free to discuss this with anyone else you wish, for example, a friend / nurse / doctor or relative. Ask us if there is anything that is not clear. We are happy to provide more information. Take as much time as you need to decide whether you want to take part.

Thank you for reading this.

What is the purpose of this study?

Applying compression to the leg is an important treatment in leg ulcer care, since it can help to improve blood flow. Compression can be applied in the form of bandages, with up to four bandages being applied to the leg at the same time, or in the form of compression hosiery (also called compression stockings). Both the bandaging and stockings approaches are used in the NHS and we are not sure which is best at healing ulcers. This is why we are conducting this study, to find out how effective compression stockings are in the treatment of venous leg ulcers when compared to compression bandaging.

What is the treatment being studied?

Traditionally, compression has been applied to the leg using layers of bandages. 4-layer compression bandaging is where four different bandages are applied to the leg, one-on-top of the other. However, more recently, compression stockings have been developed which deliver the same amount of compression as layers of bandages. Compression stockings are made of two stockings that are worn over one another at the same time. These stockings have been specially designed so that the second layer is able to slip easily over the first. We are comparing compression stockings with 4-layer compression bandaging.

Why have I been chosen?

Your nurse and / or doctor think that the type of leg ulcer you have means that you could take part in this study. We hope about 490 people with leg ulcers will take part in this study from across the UK.

Do I have to take part?

Participation in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. If you do agree to take part in this study and decide at a later time that you would like to withdraw from the study, then you are free to do so at any time. Your decision will not influence your future care or treatment.

What will happen to me if I agree to take part?

We are interested in how quickly leg ulcers heal, and also in your opinion about the compression treatment you receive. If you agree to take part in this study you will be allocated to one of two treatments: treatment with 4-layer compression bandaging or treatment with compression stockings. The decision regarding which treatment you receive will be made after you agree to take part. The choice of treatment will be determined at random, that is, no-one, including your doctor or nurse, can predict which treatment you will receive. You will have an equal chance of receiving either treatment, in the same way that tossing a coin gives an equal chance of getting 'heads' or 'tails'. This type of study where the treatment is determined randomly is called a randomised controlled trial. One out of every two people in this trial will receive compression stockings.

What do I have to do?

You will continue seeing your nurse for your leg ulcer treatments. We do not anticipate that you will have to see the nurse or doctor more frequently than you would normally do.

At the start of the study, your ulcer will be measured and photographed, and then photographed again at regular intervals. We will send you a questionnaire 1 month after you start the study to ask you about your views on your treatment. At 3, 6, 9 and 12 months after you start the study, a questionnaire will be sent to you, asking about your general health.

We are also testing a new questionnaire which measures the impact of leg problems upon your daily life. We will send you this questionnaire 2 weeks and 4 months after you start the study.

The study will last for 12 months. If your ulcer heals during the study, we will still send you questionnaires and your nurse

will also be in contact with you to monitor your progress.

There are no restrictions on your activity when you are in this study. You will continue with any other medical care or treatments, such as taking regular medication, as you would normally do. There are no limitations on you seeking other medical advice, if you need to, whilst you are taking part in this study.

Why are we doing the study?

Compression stockings may or may not be more effective than using 4-layer compression bandaging but we do not know if this is the case. It is therefore important to carry out this study so leg ulcer patients can be provided with the most appropriate and effective care. Without this information patients may receive inefficient care, and precious NHS money may be wasted.

Are there any alternatives to the treatments being studied?

There are alternative treatments available for the treatment of venous leg ulcers and your nurse will be happy to discuss other treatment options with you, if you wish. However, compression therapy is currently the most effective treatment for venous leg ulcers. Compression therapy can be applied using either bandages or stockings, but we do not know which of these is the best for treating venous leg ulcers.

Are there any side effects from the treatments being investigated?

Side effects to either treatment being used in this trial are uncommon. Whilst we do not anticipate any specific side effects as a result of taking part in this trial, in extremely rare circumstances, some patients may be allergic to materials which are contained within the bandages or hosiery. If this is the case, we will use another product which does not contain that material.

Are there possible disadvantages to taking part?

We do not anticipate that being in this trial will harm you. Should this occur, however, normal NHS negligence procedures apply. If you have any medical queries or in an emergency you should contact your doctor or nurse as you would normally do. The name of a contact research nurse responsible for this research study in your area and the telephone number where they can be reached is provided below. We have also provided the number of the person responsible for running this study, who is based at The University of York. We can not guarantee that the research

nurse or person running the trial will always be available to take your call (some research nurses work part-time) but we will always return your call as quickly as we can.

What are the possible advantages of taking part?

We hope that your ulcer will improve with either of the treatments being tested (compression bandages or compression stockings). Although we are unable to guarantee that your ulcer will improve by your being in the trial, the information we get from this study may help us to better treat people with venous leg ulcers.

What if new information becomes available?

Sometimes during a research project, new information becomes available. If this happens, your nurse / doctor will tell you about it. They will discuss with you whether you want to continue in the study. If you decide to withdraw from the study your care will continue as it would normally. If you decide to continue, then you will be asked to sign an updated consent form.

If new information means that your nurse / doctor decides to take you out of the study, then she / he will discuss this with you. He/she will explain the reasons for this and arrange for your leg ulcer care to continue as it normally would outside of the study.

What happens when the research study stops?

Both treatments being evaluated are available to every nurse / doctor in the UK. After the research stops both treatments are likely to continue to be available throughout the UK.

What if something goes wrong?

If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. At the beginning of the trial we will record your name and address and ask you to sign a consent form. This information

will be stored securely at the University of York. We will also let your GP know that you are taking part in the trial, and which treatment you are receiving. All further information about you that leaves hospital/surgery/home will not contain your name or address, so you cannot be recognised from it. This includes digital photographs of your ulcer that will be taken during the study. These will be sent by e-mail or posted. Again, these images will not have your name or any details about you on them.

If you consent to take part in the research, the University of York (for purposes of checking data collection) may inspect your medical and nursing records. People from regulatory authorities may also look at your records to check that the study is being carried out correctly.

What will happen to the results of the study?

The results of the study will be published in medical and nursing journals. You will be able to obtain a copy of the results from the University of York upon request, when these become available. You will not be identified in any publication arising from this study.

Who is organising and funding the research?

The study is being funded by the National Institute for Health Research. Your nurse or doctor is not personally receiving any money for including you in the trial. The study is being organised by researchers from the University of York.

Who has reviewed the study?

Your Local Research Ethics Committee has approved this study.

What do I do now?

If you are interested in taking part please sign the consent form, returning it to your study nurse.

Where can I get more information about the study?

If you do not understand anything on this information sheet or would like further information, please contact your nurse on the telephone number below.

Research nurse:

Alternatively you can contact the Study Coordinator:

Where can I get more information about taking part in research?

If you would like general advice about taking part in research, you can contact the Patient Advice and Liaison Service (PALS). You can contact you local PALS by phoning your local hospital, clinic, GP surgery or health centre and asking for PALS, or by phoning NHS Direct on 0845 4647, or via the web at http://www.pals.nhs.uk/