The ROSE Study: A Realist Evaluation of 'Dry' And 'Paste' Compression Bandages

INFORMATION SHEET FOR PATIENTS AND CARERS

You are invited to take part in a research project undertaken by a team of researchers from the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and Northumbria University.

Before you decide whether or not to take part, it is important that you understand why the study is being carried out and what taking part will involve. Reading through this leaflet and discussing it with others if you wish, will help you decide whether or not you would like to take part in the study. Please contact the researchers named below if you would like to ask any questions.

Study clinical researcher
Dr Fania Pagnamenta – Nurse Consultant

Noala Parr – Research Nurse

Title of the study
A realist evaluation of 'dry' and 'paste' compression bandages**.**

Summary
In this research study we will use information from yourself, your nurse and the compression bandages we use on your legs. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. Once we have finished the study, we will keep some of the data so we can check the results.

We will make sure no-one can work out who you are from the reports we write.

This information sheet will tell you more about this.

What are the aims of the study?
This study aims to provide explanations of when, for whom and in what circumstances are dry or paste compression bandages, commonly used for the treatment of lower limb ulceration, best used for?

Why have I been chosen as someone who might take part?
You are invited to take part in the study, because you are suffering with leg ulcers.

Do I have to take part?
No. It is entirely up to you whether or not you would like to take part. If you decide not to take part in the study this will not affect the care you receive in any way. If you decide to take part in the study, you may stop at any time point, without giving a reason.

What will taking part involve?
If after reading this information and having had the opportunity to ask questions, you decide you would like to take part, the research nurse responsible for the study will firstly confirm that you are suitable for the study. S/he may need to ask you some questions about your medical history to understand whether you can take part in this study. The research nurse will visit you at your home. You will then be asked to read and sign the informed consent form. We will be using an electronic tablet instead of a paper document and you will be asked to sign the consent form on the tablet.

The research nurse will also sign the form. You will be in the study for eight weeks.

Start of the study
Noala Parr, the research nurse will visit you at the place where you normally have your wound dressed, for example at your home or at the ambulatory clinic, to collect information on medical history, your legs and to ask you to complete a questionnaire on your general quality of life. The research nurse will ask you questions about pain and how itchy your legs are.

During the study
The research nurse will visit you on the first day of the study (Day 1), after one week (Week1), after four weeks (Week 4) and after eight weeks (Week 8) which is the last day of the study. If you usually have your wound dressed at home, the research nurse will visit you at home during the study.

On each visit the research nurse will ask you to complete questionnaires on how much pain you have and how itchy your legs are. The research nurse will collect information on your wound at each visit and take photographs.

Your legs will be bandaged using two types of bandages. One leg will be bandaged using a dry bandage and one leg will be bandaged using a wet bandage. A wet bandage is a bandage that has either zinc or calamine on the first layer; a dry bandage has no wet component. Both systems are currently used, but we do not know which system works best under which circumstances.

Which leg receives what treatment will be decided using a process called ‘randomisation’, which means that each leg will have the same chance of being treated either with a wet

bandage or a dry bandage. The Research Nurse will open a sealed envelope which will tell her what type of bandage to apply to your left leg and what bandage to apply to your right leg. The Research Nurse will have no prior knowledge to the instructions contained in the envelope.

End of the study

At the end of the study, you will be able to continue with different bandages on your legs or choose the one that you liked best.

If you wish so, a lay summary of the results will be sent by post to yourself after the end of the study. Please advise the Research Nurse if you wish to receive it. Your contact details will be kept for this purpose.

Will my taking part in the study be kept confidential?

Yes. All the study questionnaires will only be read by members of the research team. We will be using REDCap, which is a secure, web-based application to store data. Access will be restricted to named authorised individuals.

Your information will be destroyed 5 years after the study is complete. A study ID will be assigned to your name to protect your identity.

Additionally, if the researchers observe any events or behaviour that risked your safety or wellbeing, then confidentiality would be broken in order to escalate this to the relevant authorities in line with Trust policies and procedures.

What are the benefits of taking part in the study?

You will be offered to try two different types of compression bandage and at the end of the study, to choose the one you like the most.

What are the disadvantages of taking part in the study?

You will be asked to give up some of your time to take part in the study. You do not have to talk about anything you do not wish to and are able to withdraw from taking part in the research, without giving a reason, at any time.

What will happen to the results of the study?

The study findings will be used to help us to understand for whom these two types of compression bandages work best for; to add to the body of knowledge that pertains to leg ulceration care and guide staff to select the right compression bandage for each patient.

Findings will be written up into a report and shared across the Trust and NHS. They will also be written up and published in journal articles and presented at conferences.

The information obtained from this work will be for research purposes and will not directly result in a change in standard of care practice within the NHS Trust.

We may use direct quotations when writing articles to be published in medical/nursing journals as well as some of the photographs of your legs that we have taken during the study.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South West - Central Bristol Research Ethics Committee.

What if I decide I no longer wish to take part in the study?
You are free to come off this study at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to participate any further, please tell the research nurse either by telephone, email or on their visit to you if you are being treated at home or on your visit to the clinic.

What if something goes wrong?
Indemnity for the management, conduct and design of the research is provided through NHS schemes.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What are my rights as a participant in this study?
You can find out more about how we use your information:

- At www.hra.nhs.uk/patientdataandresearch.
- By asking one of the research team
- By sending an email to nuth.dpo@nhs.net
- By ringing us on 0191 2138946

Who is organising and funding the research?
This research is sponsored by the Newcastle upon Tyne Hospital NHS foundation Trust. Funding for this study has been provided through an unconditional grant from Milligan Healthcare Inc.

Payment
There will be no payment given to you for participating to this study.

Who to contact

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask question later, you may contact any of the following:

- Dr Fania Pagnamenta - Nurse consultant – fania.pagnamenta@nhs.net 0191 2824954.

If you wish to contact someone independent about this research, please contact:

- Mrs Cheryl Teasdale – Associate Director of Nursing - Cheryl.teasdale@nhs.net 0191 2137187.

Complaining

You can contact

- the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202 or
- NuTH Patient Relations Department to:

Telephone: 0191 223 1382 or 0191 223 1454

Email: nuth.patient.relations@nhs.net

Address: Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust

The Freeman Hospital, Newcastle upon Tyne, NE7 7DN

ADDITIONAL INFORMATION

You will find more information: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document.