CUPRA trial

North Cumbria Integrated Care NHS Foundation Trust

Patient Information Sheet for CUPRA trial

Prospective, randomised controlled trial assessing MedCu copper dressing for leg ulcer management (Chief Investigator: Jane Todhunter)

Short title: Copper dressings for Ulcers; Prospective Randomised Appraisal (CUPRA)

- We are sorry that you have a lower limb ulcer and we would like to invite you to participate in a research study. Before you decide, you need to understand why this study is being done and what it will involve for you.
- Please take time to read the following information carefully.
- Talk to others about the study if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this.

Who is carrying out the study and why?

This study has been developed and is carried out by the North Cumbria Integrated Care NHS Foundation Trust (NCIC) and partner NHS Trusts. The Chief Investigator is Jane Todhunter, vascular specialist nurse, in collaboration with the North Cumbria NHS' research department.

In patients with a leg or foot ulcer, healthcare professionals use wound dressings to help manage their symptoms and heal the ulcer. Dressings can help reduce the risk of infection and aid in wound healing.

In this study we are comparing the effectiveness of a relatively new wound dressing product with current standard care. This product is called MedCu; it is a dressing that contains copper-ions. Copper has been shown to be anti-microbial (it can kill bacteria) and there is also some evidence that it may aid with wound healing. However, more evidence is needed to demonstrate whether this is the case in a NHS care setting. The MedCu dressing will be compared to standard usual care. In most patients this will be a 'standard' dressing but it may also involve treatment with another anti-microbial dressing (if clinically indicated). By

randomising patients to two different treatment groups, an overview can be obtained on the relative effectiveness of MedCu dressing.

Why have I been invited?

The clinical staff treating your lower limb has determined that you have an ulcer and that this needs to be dressed to help relieve symptoms and aid wound healing. They have identified you by screening your notes or in clinic, and will ask you if you potentially wish to take part in this study. You may already be having the ulcer dressed as part of your usual care. If you are interested, then they will ask your verbal consent for one of the research team to talk you through the study. Either way, you will be managed for your leg(s) as you normally would – if there is a change in your needs in relation to the dressing of your wound whether you are in the trial or not. In other words, not taking part in this study does not affect the care you receive. We anticipate 66 patients to take part in this study.

Do I have to take part?

No. It is not compulsory for any patient to take part; it is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us about anything that is not clear or if you would like more information. Regardless of whether you decide to take part or not, your clinical treatment will not be affected by your decision. If you do decide to take part, you are free to withdraw at any time without explanation and this will not affect the standard of care you receive in any way. In case of not taking part, your treating clinician will treat you as per usual standard care.

What will happen to me if I take part?

If you decide that you may want to take part in the study, one of the research staff, which may be the chief investigator or a trained and delegated member of the study team, will take written consent from you. You will be given more than 24 hours to decide whether you would like to participate and ask any questions you may have, you do not have to consent when you are first approached about this study. We ask permission to access your medical records to record data related to your leg care. We also ask permission to inform your General Practitioner (GP) of your participation in the study.

Your participation is completely voluntary and will be for 12 weeks. Once you have consented to taking part, you will be asked to complete some questionnaires regarding your leg (we will only focus on one leg for the study for the collection of data). At each visit, combined these take about 5 minutes to complete. The researcher and/or clinical staff can assist you with answering the questions if you wish. A summary of the questionnaires to be answered is summarised below.

You will then be randomised to one of two treatment arms – this means you have a 50% chance of receiving either treatment option. The research study visits usually coincide with standard clinic visits. At those four visits (week 0, week 4, week 8, and week 12) your ulcer will be examined, and the wound measured if it still present. After the 12 week trial period, clinical staff will recommence managing you as per your routine care. If your ulcer heals within the 12 week study period, then it may be possible that a dressing is no longer needed, but the treating clinical staff will discuss this at that point. We would ask all participants to complete all the follow-up visits (option to do this remotely) even in cases where they no longer have an ulcer.

Table 1, Timeline and overview of different study visits

Type of visit	**Point of contact**	**What will happen?**

Week 0	Clinic (for example vascular department or podiatry)
	To coincide with standard clinic appointment where possible
		• Written Informed Consent
		• Collection of general information (age, general health)
		• Measure ulcer size
		• Questionnaires:
		  ○ Quality of life (general)
		  ○ Symptoms (specific to leg)
		  ○ Pain score (specific to leg)
		• Photo of leg ulcer location (optional)

Week 4,
Week 8, and week 12
	Clinic (for example vascular department or podiatry)
	To coincide with standard clinic appointment where possible, or possibly remotely if ulcer healed at last visit
		• Check if leg ulcer has healed
		• Measure ulcer size, if still present
		• Questionnaires:
		  ○ Quality of life (general)
		  ○ Symptoms (specific to leg)
		• Photo of leg ulcer location (optional)

What are the possible benefits of taking part?

The treatment you receive will not differ from the standard treatment options available, and hence the risks are very low. This means that if you do not take part in the study, then you will most likely be prescribed one of the wound dressings as part of your normal regular care.

Because this study will use wound dressings that are also used in standard care, there is no anticipated immediate benefit to you. However, there is a chance that one of the two dressing treatments that are studied may be more effective. At present we do not know this and the CUPRA trial is designed to find out if this is the case. You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

Patients who take part can receive a copy of a summary of the study results, to inform them how the two bandage brands performed in this study.

What are the possible disadvantages and risks of taking part?

There are no major personal safety risks anticipated regarding taking part in this research trial. Dressings themselves may potentially lead to some skin irritation and discomfort. If you do decide to take part in the CUPRA trial, and your National Health Service (NHS) Trust, surgeon, GP, nurse or the research team learns of important new information that might affect your desire to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

How will we use information about you?

We will need to use information from your medical records for this research project.

This information will include your name, sex, age and contact details (address and phone number). People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Some of your information (study outcome data) will be sent to the funder of the research, Creed Health, based in the UK. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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.

Will my participation in the study be kept confidential?

A member of your direct care team has screened your details to ensure you are eligible to take part in the study; these details will not be shared with anyone else in the research team. All information that you give us will be kept strictly confidential. You will be asked to give your name and contact details because we wish to match this with your medical information.

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act and General Data Protection Regulation for health and care research. Your data collected during your participation in the CUPRA trial will be entered into a password-protected database and analysed – using only NHS computers and servers. For the data analyses, your study data will not be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor's clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor's auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to the study files, but your medical records will not be accessed.

We will need to use information from you and from your hospital medical records for this research project. This information will include your name. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What if something goes wrong?

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below). The study is covered by NHS

insurance in relation to the design, management and conduct of the research, but not for no fault compensation.

What will happen if I don't want to carry on with the study?

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will continue treating you as he or she normally would and you do not have to give a reason as to why you wish to withdraw from the study. In this instance, we would be grateful if – where possible - you can inform us that you wish to withdraw when you see the vascular team at one of your scheduled clinic appointments, or by contacting us by phone or email (see section 'Contact for further information' at end of this leaflet for details). If you withdraw after signing the study consent form, you will not be able to re-enter the study. Any data collected up to the point where you withdraw will be retained for analysis as part of the study. The latter also applies if you were to lose capacity to take part during the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information
•at www.hra.nhs.uk/information-about-patients/
•our leaflet available from www.hra.nhs.uk/patientdataandresearch
•by asking one of the research team, further down this leaflet at 'Contact for further information'
•Within the sponsor NHS Trust for this study via the Data Protection Officer pals@ncic.nhs.uk

Who is organising and funding the study?

North Cumbria Integrated Care NHS Foundation Trust is the sponsor for the study, and MedCu Technologies will provide a one of the dressings – called MedCu copper-ion impregnated dressing - to the study team. Specialist vascular nurse Jane Todhunter is the chief investigator for the study. Creed Health, based in the UK, has provided a non-restricted research grant to fund this project. This means that, although external funding has been received, the results of the study will be reported on and published by the NHS research team without interference from the grant provider. The study has been reviewed and given a favourable opinion by the National Ethics Research Service (North of Scotland (1) Research Ethics Committee, REC Reference 25/NS/0020), the Health Research Authority (reference 350241) and the NHS Trust (North Cumbria Integrated Care NHS Foundation Trust) which is one of the locations where the study is conducted.

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

Contact for further information

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the CUPRA research team:

- Name: Mrs Jane Todhunter (Chief Investigator)
- Phone number: 01228 814751
- Email: Research@ncic.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team (PET), tel 0800 633 5547 or PET@ncic.nhs.uk , or from websites such as the NHS Choices website, http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Independent advice can be obtained from the Patient Advice & Liaison Service (PALS)

Email: pals@ncic.nhs.uk , Telephone: 01228 814008

Thank you for taking the time to read this information sheet