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The evaluation of MedCu copper wound dressing, compared to standard care, for management of foot and leg ulcers

Submission date
12/03/2025

Recruitment status
Recruiting

Registration date
13/03/2025

Overall study status
Ongoing

Last Edited
24/04/2025

Condition category
Not Specified

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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. This study aims to compare 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 antimicrobial (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 an 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 antimicrobial dressing (if clinically indicated). By randomising patients to two different treatment groups, an overview can be obtained of the relative effectiveness of MedCu dressing.

Who can participate?
Adult patients (aged 18 years or over, and women of non-childbearing potential) with a foot or leg ulcer of a size between 1 and 30 cm2. The ulcer can have been present for more than 30 days to less than 1 year from the patient becoming aware of the wound in question.

What does the study involve?
The study involves patients being seen at weeks 0, 4, 8 and 12. At week 0 patients are randomly allocated to either standard care (control patients) or treatment with MedCu copper-impregnated wound dressings for the management of their main ulcer. Since copper ions kill bacteria and have been shown to stimulate blood vessel development in wounds, this dressing may possibly have beneficial effects on wound healing (and this is what is being evaluated in this study). The choice of standard care wound dressing can be decided by the usual treating clinical staff; this may involve a standard dressing or another dressing designed to kill bacteria such as silver-impregnated dressing.

What are the possible benefits and risks of participating?
The treatment patients receive will not differ from the standard treatment options available,

and hence the risks should be very low. This means that if patients do not take part in the study, they will most likely be prescribed one of the wound dressings as part of normal regular care (MedCu copper-impregnated dressing is also available to clinical staff outside this study, though it is locally not listed on the so-called NHS formulary of preferred wound dressing products). Because this study will use wound dressings that are also used in standard care, there may not be an immediate benefit to the patient. 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 this study is designed to find out if this is the case. Patients 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. There are no major personal safety risks anticipated regarding patients taking part in this research trial. Dressings themselves may potentially lead to some skin irritation and discomfort; allergy to copper is a very rare occurrence. If patients do decide to take part and the National Health Service (NHS) Trust, surgeon, GP, nurse or the research team learns of important new information that might affect their desire to remain in the study, they will tell the patient as soon as possible. Appropriate precautions are in place to ensure patients' medical and personal information is kept safe.

Where is the study run from?
North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2024 to July 2026

Who is funding the study?
Creed Health (UK)

Who is the main contact?
Dr Leon Jonker, Leon.jonker@ncic.nhs.uk

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
350241

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67069

Study information

Scientific Title
Prospective, randomised controlled trial assessing MedCu copper dressing for leg ulcer management

Acronym
CUPRA

Study objectives
This study will aim to determine if treatment of lower limb ulcers with a copper-oxide particle impregnated dressing (called MedCu, or ‘copper dressing’) can aid in accelerated wound healing of lower limb ulcers when compared to standard care dressings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2025, North of Scotland Research Ethics Committee (1) (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 25/NS/0020

Study design
Randomized; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Leg ulcer

Interventions
Written informed consent will be taken from the patients. Thereafter, they are randomised to one of two treatment arms (standard care or MedCu copper dressing). Patients will be in the trial for 12 weeks, with outcome measures being taken at weeks 0, 6 and 12. If during this period

wound dressing is no longer indicated then it will no longer be applied but outcome measures will still be taken.

At baseline (week 0),4, 8 and 12 weeks, various validated questionnaires will be completed by the participant (focussing on quality of life) and essential clinical information will be recorded.

As mentioned, relevant baseline clinical information and any changes in the condition of the leg and patient will be recorded too, including any safety outcomes.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Ulcer wound status (healed or not healed) and dressing (used or not used, and which type) will be recorded at week 0, week 4, week 8 and week 12

Key secondary outcome(s))
1. Ulcer wound size will be measured with the Healthy io App (digital wound size measurement) and validated PUSH score questionnaire at week 0, week 4, week 8 and week 12
2. General quality of life will be measured with validated EQ-5D-5L questionnaire at week 0 and week 12
3. Ulcer-related symptoms will be measured with validated VEINES-Sym questionnaire at week 0, week 4, week 8 and week 12

Completion date
30/07/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Women to be of non-childbearing potential (i.e., postmenopausal)
3. Lower limb ulcer sized between 1 and 30 cm2
4. Patients can be newly presenting to or existing users of the specialist service in question
5. Patients with recurrent wounds, including multiple wounds, are eligible; largest eligible (i.e. <30 cm2) ulcer to be index wound
6. If infection occurs and systemic antibiotics are applied whilst in the study, then this is not deemed an exclusion criterion.
7. Chronicity: clinical diagnosis of ulcer with wound duration > 30 days and < 1 year from patient becoming aware.
8. Prophylactic systemic antibiotic use is not an exclusion criterion
9. Mental and physical ability to give consent and complete study activities
10. Pure foot ulcer, i.e. any ulcer that commences below the malleolar region (particularly plantar, digital regions)
11. Underlying pathology of leg ulcer can be venous, mixed venous-arteria, arterial, or through different underlying aetiology. Recognised comorbidities that may contribute to the development of leg ulcers (e.g. diabetes, rheumatoid arthritis, peripheral vascular disease) are not an exclusion criterion.

12. For leg ulcers: patient is suitable for, and willing to wear, compression therapy, or valid clinical reason why they should not be prescribed compression therapy.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Limited life expectancy, i.e. undergoing palliative care, or other condition that in the opinion of the researcher contraindicates participation
4. Active infection in leg ulcer treated with systemic antibiotics within last 1 week (does not apply for prophylactic antibiotic regimes)
5. Enrolled in other interventional research studies related to patient's lower limb ulcer
6. Previous participation in the CUPRA study
7. Awaiting significant surgical intervention related to the vascular or skeletal system of the lower limbs, planned within 3 months (i.e., 12-week trial period)
8. Known intolerance or allergy to materials used in MedCu copper dressing

Date of first enrolment
23/04/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary

Infirmary Street
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Creed Medical Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The researchers intend to share with/submit to the scientific journal the anonymised outcome dataset

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	06/03/2025	12/03/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	18/10/2024	12/03/2025	No	No