ISRCTN37496076 https://doi.org/10.1186/ISRCTN37496076

Clinical trial of reduced leg compression for the treatment of leg ulcers, a randomised controlled trial

Submission date
09/03/2023

Recruitment status
No longer recruiting

Registration date
17/03/2023

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Leg ulcers are a difficult problem to manage and treat, as they can become chronic, infected, and require surgery. This not only negatively affects the patient's life but also creates a financial burden on the National Health Service. Compression bandaging is the main treatment option, and it's important that patients comply with it to increase the chances of healing and reduce complications. However, even with improvements in compression bandages, patients still experience discomfort and itching. A new bandage called Andoflex TLC Calamine Lite has shown promise in reducing discomfort and potentially speeding up the healing process. This study will randomly assign leg ulcer patients to one of two bandages: Andoflex TLC Calamine Lite or 3M's Coban 2 Lite. The goal is to determine which bandage is more effective at promoting healing over 12 weeks.

Who can participate?
Patients aged over 18 years, with leg ulcers, who can't use full compression bandaging

What does the study involve?
In total, 92 patients are planned to be enrolled and for clinical reasons these patients cannot be administered full compression bandaging and are hence administered reduced ('Lite') compression bandaging. Outcome measures will be wound healing rates, by measuring the size of the ulcer, and also the level of patient reported quality of life. For this, participating patients attend a clinic at week 0, week 6 and week 12.

What are the possible benefits and risks of participating?
Both the Andoflex and Coban products are authorised to be used for the treatment of leg ulcers and therefore all trial participants will benefit from active treatment. As such, there are no additional risks of taking part in the trial; there are known side-effects that may happen with any compression bandage, such as discomfort or a reaction to the bandage materials. One of the devices may perform better than the other, but only by doing this trial can we determine if this is the case.

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?
December 2022 to October 2024

Who is funding the study?
Milliken Healthcare Products, LLC (UK)

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

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
280418

Central Portfolio Management System (CPMS)
54514

Study information

Scientific Title
Prospective Evaluation of Applied ‘Lite’ Compression for leg ulcer Healing, a pragmatic, multi-centre randomized controlled non-inferiority trial

Acronym
PEACH

Study objectives
To determine the relative efficacy of two-layer Lite compression bandaging for the management of leg ulcers, measured through wound status (healed vs non-healed) at 12 weeks post-baseline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2022, South West - Frenchay Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 104 8121; frenchay.rec@hra.nhs.uk), ref: 22/SW/0158

Study design
Interventional randomized controlled trial

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 (Andoflex or Coban2). Patients will be in the trial for 12 weeks, with outcome measures being taken at week 0 week 6, and week 12. If during this period compression bandaging is no longer indicated then it will no longer be applied but outcomes measures will still be taken.
At baseline (week 0), 6 weeks and 12 weeks, various validated questionnaires will be completed by the participant (focussing on quality of life and pruritus) 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
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AndoFlex TLC Calamine Lite or 3M’s Coban 2 Lite bandage

Primary outcome(s)
1. Ulcer wound status (healed or not healed) and compression bandage use (used or not used) will be recorded at week 0 , week 6 and week 12
2. Ulcer wound size will be measured with a wound grid device and validated PUSH score at week 0 , week 6 and week 12
3. Ulcer related pain and pruritus will be measured with respective 10-cm visual analogue scales at week 0 , week 6 and week 12.
4. General quality of life will be measured with validated EQ-5D-5L questionnaire at week 0 , week 6 and week 12

5. Ulcer related quality of life will be measured with validated VEINES-QOL questionnaire at week 0 , week 6 and week 12

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
23/10/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Underlying pathology of leg ulcer is venous or mixed venous-arterial. Recognised co-morbidities that may contribute to the development of leg ulcers (e.g. diabetes, rheumatoid arthritis, peripheral vascular disease) are not an exclusion criterion.
3. At least one leg ulcer (in case of multiple defined ulcers, single largest measurable ulcer will be classed as index ulcer). Leg ulcer defined as any break in the skin on the lower leg that has been present for 2 weeks (from NICE 2013)
4. Tolerating compression bandaging
5. Mental ability to give consent
6. An ankle–brachial pressure index (ABPI) of >= 0.5 – 0.8 taken within the previous 3 months. Where an ABPI measure is not viable, use of locally-approved alternative diagnostic assessments to rule out significant peripheral arterial disease and/or ischaemia, i.e. by pulse palpation and ultrasound diagnostics, toe pressure assessment or arterial imaging. If ABPI or other diagnostic methodology is not indicated or feasible, recorded clinical assessment by qualified clinical staff is allowed (diagnosis and rationale for reduced compression to be recorded at baseline).
7. Patient is allowed to be on compression therapy prior to enrolment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
78

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 opinion of researcher contraindicates participation
4. Active infection in leg ulcer treated with antibiotics within last 1 week (does not apply for prophylactic antibiotic regimes)
5. Is not willing or able to wear any compression device
6. Pure foot ulcer, ie any ulcer that commences below malleolar region (particularly plantar, digital regions)
7. Enrolled in other interventional research study related to patient's leg ulcer
8. Previous participation in PEACH trial
9. Awaiting surgical intervention related to vascular system of the lower limbs, planned within three months
10. Wound size that is too small (typically <1 cm^2), or too large (larger than single wound grid or extending round the leg) to measure accurately
11. Known intolerance or allergy to materials used in compression bandaging (including zinc oxide, calamine).

Date of first enrolment
01/10/2022

Date of final enrolment
23/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
England
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Milliken Healthcare Products, LLC

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2025	18/11/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.1	02/12/2022	17/03/2023	No	Yes
Plain English results	version 2024	05/11/2024	18/11/2025	No	Yes
Protocol file	version 1.1	02/12/2022	17/03/2023	No	No
Protocol file	version 2.0	21/06/2023	17/04/2024	No	No