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Compression therapies for the treatment of venous leg ulcers

Submission date 07/09/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/09/2020	**Overall study status** Completed	
Last Edited 20/01/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Venous leg ulcers are common, recurring open wounds on the lower leg. Compression is the first line of treatment for venous leg ulcers. A range of compression therapies such as four-layer bandages two-layer hosiery, two-layer bandages and compression wraps are regularly used in the NHS. However, we are unsure whether one compression therapy is more effective at treating venous leg ulcers than the others. Therefore, this study will aim to investigate the clinical and cost-effectiveness of compression therapies for treating venous leg ulcers.

Who can participate?
Adults with a venous leg ulcer

What does the study involve?
Following obtaining consent, eligible participants will be asked to complete a baseline questionnaire asking about their health and ulcer(s) and have a photo taken of their reference ulcer (as determined by the recruiting healthcare professional). Participants will then be randomly allocated to one of three treatment groups:
1. Compression wraps (adjustable hook-and-loop-fastened compression): A compression sleeve around the foot and leg
2. Evidence based compression (Four-layer bandage or two-layer compression hosiery):The participant and their healthcare professional will decide which treatment they receive. This will be either four layers of compression bandages or two layers of compression stockings
3. Two-layer compression bandage: This bandage will comprise of an initial bandage layer with a top compression bandage

Participants will then continue to see their healthcare professional for routine ulcer treatments to be carried out as normal. The healthcare professional will check how the ulcer is healing and record details of any changes to their treatment. Clinical events such as reference leg healing, ulcer recurrence, amputation, admission and discharge or death will also be recorded if and when they occur.

Once the participant's ulcer has healed, a photograph of the reference ulcer will be taken once a week for 4 weeks. Following the healing of the leg ulcer, a nurse will also contact the participant once a month, by telephone, to check that the ulcer has not returned.

Whichever treatment a participant receives, they will be asked to complete a questionnaire booklet at 1, 3, 6, and 12 months, asking about their health and ulcer(s). These questionnaires will be sent in the post with a prepaid envelope for their return. A £10 voucher will also be sent to participants at 12 months to thank them for their time.

At the end of the study, participants will return to standard NHS care with their treatment nurse or doctor. If their ulcer does not fully heal during the study the participant's care will continue with the treatment their doctor or nurse feels is best.

What are the possible benefits and risks of participating?
Every effort will be made to improve a participant's venous leg ulcers; however, we cannot say whether the ulcer will improve more quickly because of participation in the study. The information we get from this study may have a significant impact upon helping people and healthcare professionals make more informed treatment choices in the future.

Side effects for compression wraps, the two-layer bandage, four-layer bandages and the two-layer hosiery are uncommon and are treatments routinely used in the NHS for patients with venous leg ulcers. There are no anticipated increased risks through participation in this study. Being in the study will not harm or disadvantage your care in any way. Throughout the study, participants will continue to see their health care professional for wound treatments to be carried out as normal.

Where is the study run from?
The study is run from York Trials Unit, University of York (UK) and 16 NHS trusts (UK)

When is the study starting and how long is it expected to run for?
From February 2020 to August 2024

Who is funding the study?
The National Institute for Health Research Health Technology Assessment Programme (Project Number: NIHR128625) (UK)

Who is the main contact?
1. Dr Catherine Arundel (public and scientific contact)
Catherine.arundel@york.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Catherine Arundel

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Type(s)
Scientific

Contact name
Prof Jo Dumville

ORCID ID
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M13 9PL
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280987

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 46547, IRAS 280987

Study information

Scientific Title
A randomised controlled trial of compression therapies for the treatment of venous leg ulcers (VenUS 6)

Acronym
VenUS 6

Study objectives
1. To compare compression wraps with evidence-based compression in terms of the time to healing of venous leg ulcers;
2. To determine whether two-layer bandages are non-inferior to evidence-based compression for time to healing of venous leg ulcers;
3. To determine which is the most cost-effective, full compression treatment for venous leg ulcers

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/09/2020, West of Scotland REC 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 20/WS/0121

Study design
Multi-centre three-arm parallel-group pragmatic randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Venous leg ulcers

Interventions
Current interventions as of 09/02/2024:
The study has a 45-month recruitment period in total (comprising and initial 32 month planned recruitment period plus 13 month extension) including an initial 6 month internal pilot. Follow-up will be variable with participants followed for minimum of 4 months and a maximum of 12 months.

Prior to study involvement the clinical care team will screen clinical caseloads at trial sites will assess participants against the eligibility criteria. Patients who may be eligible to participate in the study will be approached by a member of the research team and provided with a patient information sheet and asked to indicate if they would be interested in participating. Patients will be given sufficient time to consider this information.

Once eligibility has been confirmed, patients must take part in the consent process. During the consent process, the person obtaining consent will inform the participant of all aspects of the trial (e.g. trial procedures, risks/benefits) in order to allow the participant to make an informed decision about their participation. No protocol specific procedures are performed until the participant has signed and dated an Ethics Committee approved informed consent form.

Once informed consent has been obtained, baseline data will be collected and participants then randomised.

At baseline participant contact details, GP contact details, diabetes status, weight, height and general mobility and ankle mobility will be determined. Ulcer history and assessment such as duration and area of the reference ulcer, number of previous ulcer episodes, ankle–brachial pressure index and ankle circumference. A photo of the reference ulcer (where a participant has multiple ulcers the reference ulcer will be defined as that with the largest surface area) will be taken in order to monitor healing.

Following collection of baseline data, the research team will contact the UKCRC-accredited University of York Trials Unit (YTU) via the internet to access a secure randomisation service, which will ensure complete allocation concealment. The randomisation service will record information and check eligibility to avoid inappropriate entry of patients into the trial. Randomisation will be stratified by ulcer duration (<6 months and > 6 months) and ulcer area (< 5cm2 and > 5cm2) using permuted blocks; these variables are known predictors of healing. Participants will be randomly allocated 1:1:1 to either:
1. Arm 1: compression wraps
2. Arm 2: evidence-based compression treatment (choice between four-layer bandage or two layer compression hosiery)
3. Arm 3: two-layer bandage Randomisation will be stratified by ulcer duration (<6 months and >6 months) and ulcer area (<5m2 and >5cm2) using permuted blocks
Once randomised, participants will begin their trial treatment as soon as it is available in line with what would happen in routine practice.

Participants will continue to receive standard care, including wound dressing changes, as per routine clinical practice. Study data on treatment use and clinical outcomes will be collected weekly during this period by the treatment team. This will include:
1. Healing of the reference ulcer. Treating nurses will be asked to report the date when they consider the reference ulcer and the reference leg has healed. Additionally, data on the reference ulcer will be collected throughout the study in the form of digital images. A digital image will be taken at baseline and again when the treating nurse records the reference ulcer as healed. After this point images will be taken once a week over the next 4 weeks. These images will be assessed by two blinded clinical experts to confirm the date of healing, with disagreements being resolved through discussion and the involvement of a third reviewer if required.
2. Treatments-received (including changes to trial treatment). treatments received will be logged every wound-related nurse visit to the participant, using a case report form, until either the participant's reference leg (the leg with the reference ulcer on) is ulcer-free and no more nurse visits are required to treat this leg or until the participant exits the trial. The date of visit, the type of compression being received, and the type of primary contact dressing being used will be recorded. These resource use data will be used in economic analyses. If a participant changes from their allocated compression treatment, the date of this change, what they changed to, and the reason for this change; including whether the change from trial treatment was requested by the patient or based on a clinical decision, will b recorded.
3. Healing of the reference leg. Although the clinical analysis defined the primary outcome based on healing of the reference ulcer, the clinically relevant outcome is healing of all ulcers (ulcer free patient). It will be assumed that the reference leg is independent of the non-reference leg (even if this has ulcers), and that healing of the reference leg is the main outcome for evaluation in the economic analysis.
4. Recurrence. Following healing of the reference leg, monthly telephone assessment for ulcer recurrence will take place until the participant exits the trial. The maximum period for trial follow-up will be 12 months following randomisation, although due to variable follow-up some participants will be followed for less time (minimum 4 months).
5. Health-related quality of life assessed using the VEnous INsufficiency Epidemiological and

Economic Study - Quality of Life (VEINES-QOL) and the EuroQol 5-dimension 5-level quality of life questionnaire (EQ-5D-5L) at baseline, and at 1, 3, 6, and 12 months follow up (sent and returned via post)
6. Ulcer-related pain will be measured using the Visual Analogue Pain Scale (VAS) at baseline, and at 1, 3, 6, and 12 months follow up (sent and returned via post)
7. Resource use will be determined through a set of questions recording the ulcer-related care from the NHS within the past 3 months at 3, 6 and 12 months (sent and returned via post)
8. Participant adherence and ease of treatment use will be determined through a set of questions assessing views on the compression treatments, volume of treatment use and reasons for reduced dose at 1, 3, 6 and 12 months (sent and returned via post)

After the final assessment, participants will return to usual NHS care.

Three studies within a trial (SWATs) are planned to assess the effectiveness for methods to improve recruitment and retention:
1. Recruitment SWAT: Evaluation of the effects of presentation of the study design to participants on recruitment rate. Participants will be randomised to receive an infographic (visual document explaining the study) plus the standard patient information sheet (PIS) or just the PIS.
2. Retention SWAT: A 2 by 2 factorial design to simultaneously evaluate the effect of two retention strategies: a participant newsletter and a thank you card sent in advance of follow up questionnaires. Participants will be randomised to receive either: a newsletter and thank you card; a newsletter only; a thank you card only; or neither the newsletter nor the thank you card. These will be sent at Month 4 and Month 9 following randomisation to the VenUS 6 trial.
3. Retention SWAT 2: The researchers will evaluate the effect of including a pen on retention rates.
Participants will be randomised to receive 1) a pen; 2) no pen. These will be sent at Month 3 following randomisation to the VenUS 6 trial.

Process Evaluation:
Understanding participant use of compression treatments
To fully understand the findings of the trial the researchers are conducting interviews to gather views and experiences on compression therapies to treat venous leg ulcers, particularly compression wraps. They will conduct semi-structured interviews of approximately 20 participants randomised to different compression treatments. The interviews will use topic guides developed from reviews of the literature on quality of life of people living with venous leg ulcers and consultations with our PPI representatives. The topic guide will explore compression adherence, ease of application, reasons for treatment change, and experiences of wearing different compression treatments. It will be iterative to allow any new themes that arise during interviews to be explored with subsequent participants. Interviews will last around an hour and will take place over telephone or preferred contact method of the participant.
The researchers will also conduct up to 10 interviews with nursing staff who deliver compression treatments, as part of VenUS 6, to gather their views and experiences on treatment delivery of compression, especially compression wraps.

Previous interventions as of 27/08/2021 to 09/02/2024:
The study has a 32-month recruitment period, including an initial 6 month internal pilot. Follow-up will be variable with participants followed for minimum of 4 months and a maximum of 12 months.

Prior to study involvement the clinical care team will screen clinical caseloads at trial sites will assess participants against the eligibility criteria. Patients who may be eligible to participate in

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Previous interventions:

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The researchers will also conduct up to 10 interviews with nursing staff who deliver compression treatments, as part of VenUS 6, to gather their views and experiences on treatment delivery of compression, especially compression wraps.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to healing of the reference ulcer, defined as 'complete epithelial cover in the absence of a scab with no dressing required. This will be measured by blinded assessment (by two independent blinded assessors, and where there is any disagreement in review, a third review may be completed) of digital images taken at baseline and when the treating nurse regards the reference ulcer as healed

Key secondary outcome(s))
1. Health-related quality of life measured using the VEnous INsufficiency Epidemiological and Economic Study - Quality of Life (VEINES-QOL) and the EuroQol 5-dimension 5-level quality of life questionnaire (EQ-5D-5L) at baseline, 1, 3, 6, and 12 months
2. Resource use measured using a set of questions recording the ulcer-related care from the NHS within the past 3 months at 3, 6, and 12 months
3. Wound-related pain measured using the Visual Analogue Pain Scale (VAS) at baseline, 1, 3, 6, and 12 months
4. Participant adherence and ease of treatment use measured using a set of questions assessing views on the compression treatments, volume of treatment use, and reasons for reduced dose at 1, 3, 6 and 12 months
5. Incidence of clinical events such as reference leg healing, ulcer recurrence, amputation, admission, and discharge or death will also be recorded if and when they occur

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. ≥1 venous leg ulcer
2. Ankle:brachial pressure index (ABPI) ≥0. 8 (taken within the previous 3 months or where an ABPI is not viable, use of locally-approved alternative assessments to rule out peripheral arterial disease i.e. pulse palpation and doppler ausculation toe pressure assessment or arterial imaging also taken within the last 3 months)
3. Able to tolerate full compression
4. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
637

Key exclusion criteria
1. Unwilling to wear full compression
2. Leg ulcers of non-venous aetiology (e.g. arterial or rheumatoid)
3. significant peripheral vascular disease which contraindicates full compression (requiring an APBI of at least 0.8)
4. Ulcers confined to the foot
5. Lacks capacity or willingness to provide consent to participate in the trial
6. Currently participating in another study evaluating treatments for their venous leg ulcer
7. Known allergy to any trial product
8. Previously recruited for this trial
9. Deemed to be not clinically appropriate to take part in the trial (at clinician discretion)
10. On a waiting list for endovenous ablation and is expected to have surgery within 28 days

Added 27/08/2021:
10. Planned treatment to close/remove incompetent superficial veins (e.g. via endovenous ablation, sclerotherapy) within 28 days

Date of first enrolment
01/10/2020

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester

United Kingdom
M13 9WL

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Kent Community Health NHS Foundation Trust
Unit D
The Oast
Hermitage Lane
Maidstone
United Kingdom
ME16 9NT

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
United Kingdom
PR5 6AW

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane

North Shields
United Kingdom
NE29 8NH

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
University hospitals birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Cambridgeshire And Peterborough NHS Foundation Trust
Elizabeth House, Fulbourn Hospital
Fulbourn
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary

Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
East Suffolk And North Essex NHS Foundation Trust
Colchester District General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Cambridgeshire Community Services NHS Trust
Unit 7/8
Meadow Park
Meadow Lane
St. Ives
United Kingdom
PE27 4LG

Study participating centre
Norfolk Community Health And Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Derbyshire Community Health Services NHS Foundation Trust
Trust Hq, Ash Green Disability Centre

Ashgate Road
Ashgate
Chesterfield
United Kingdom
S42 7JE

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128625

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised datasets generated and analysed during the current study will be stored in a publicly available open research repository (https://osf.io/echxv). Data is anticipated to be available via this repository by the end of 2024, following the completion of analysis and subsequent publication. Sharing of this anonymised data is covered by original participant consent for the VenUS 6 trial which permits sharing of data to support future research via sharing anonymously.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/05/2023	30/05/2023	Yes	No
Protocol article	process evaluation	14/11/2023	16/11/2023	Yes	No
Other files	Evidence synthesis analysis plan version 1.0	19/03/2024	04/07/2024	No	No
Other files	Health economics analysis plan version 1.0	19/03/2024	04/07/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1.0	24/11/2023	09/02/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes