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VenUS IV: compression hosiery versus compression bandaging in the treatment of venous leg ulcers

Submission date
03/03/2009

Recruitment status
No longer recruiting

Registration date
17/03/2009

Overall study status
Completed

Last Edited
26/05/2016

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Venous leg ulcers are common chronic wounds that are painful and reduce quality of life. Treatment of these wounds costs the NHS millions of pounds per year. Having a venous leg ulcer is normally a sign of underlying problems in the leg veins. If these veins are damaged or blocked in some way, blood flow is affected which in turn may lead to skin breakdown and impaired healing. Compression bandaging is known to be effective for healing venous leg ulcers, but this technique requires skill, and bandages can be dangerous if they are too tight. The bandages also take time to apply and often require changing by a nurse once or twice a week. Finally, some patients do not like wearing the bandages because they find them unattractive, cumbersome and uncomfortable. An alternative to bandaging is compression hosiery (below knee stockings), which requires less skill to apply than bandages, can be applied by patients and may be more comfortable for them. However whilst stockings are available on the NHS, they are not currently widely used as a treatment for leg ulcers as they are unproven. The aim of this study is to compare compression bandaging with compression hosiery in the treatment of venous leg ulcers.

Who can participate?
Patients aged 18 or over with at least one venous leg ulcer

What does the study involve?
Participants are randomly allocated to be treated with either compression hosiery or compression bandaging. Treatment continues for as long as required. We collect data on how quickly ulcers heal when they are treated with either bandages or hosiery, as this is obviously an important outcome for patients. We also collect data to investigate the cost effectiveness of both treatments and adverse events to monitor patient safety.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
May 2009 to April 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Jo Dumville
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/60/26

Study information

Scientific Title
VenUS IV: a randomised controlled trial of compression hosiery versus compression bandaging in the treatment of venous leg ulcers

Acronym
VenUS IV (Venous leg Ulcer Study IV)

Study objectives

Venous leg ulcers are treated with compression to promote healing. An evidence-based compression treatment is 4-layer bandaging however, compression hosiery may offer advantages over this treatment. The trial aims to assess the clinical and cost effectiveness of compression hosiery compared with 4 layer bandaging in terms of ulcer healing and quality of life in venous leg ulcer patients.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/076026
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/51907/PRO-07-60-26.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration – submission pending

Study design
Pragmatic two-armed parallel randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The participants will be randomly allocated to the following two arms (randomisation ratio 1:1):

Intervention group: Compression hosiery
Control group: Four-layer bandaging

Interventions will be received for as long as required i.e. until healing or cessation of trial treatment for another reason. Total duration of follow-up is 12 months.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Time to ulcer healing. Total duration of follow-up: 12 months.

Secondary outcome measures
1. Cost of treatments. Total duration of follow-up: 12 months.
2. Quality of life (QOL), assessed by SF-12® Health Survey, Euroqol EQ-5D, and Venous Insufficiency Epidemiological and Economic Study (VEINES)-QOL questionnaire every 3 months for 12 months
3. Patient concordance with treatment. Any changes to treatment will be recorded by nurses throughout the trial (Total duration of follow-up: 12 months). At 1 month, a postal questionnaire will be sent to participants in the intervention group to collect data on how often they wear the hosiery.
4. Recurrence. Total duration of follow-up: 12 months.

Overall study start date
01/05/2009

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 years or over
2. Patient has at least one venous leg ulcer*
3. Patient has an ankle brachial pressure index (ABPI) equal to or greater than 0. 8 and <1.2 (taken within last 3 months)
4. Patient is able and willing to tolerate high compression

*For the purpose of this study a leg ulcer will be considered as any break in the skin on the leg (below the knee and above the malleoli) which as either (a) been present for more than six weeks or (b) occurs in a person with a history of venous leg ulceration. A participant will be considered to have a purely venous leg ulcer where clinically no other aetiology is suspected. Clinical history must be considered and the study participant must have an ABPI of equal to or greater than 0.8. The ulcer must also be venous in appearance (i.e. moist, shallow, irregular shape, venous eczema, ankle oedema).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
489

Key exclusion criteria
1. Leg ulcer of non-venous aetiology (i.e. arterial)
2. Wound exudate levels too high for the use of compression hosiery (nurse judgement)
3. Patient has very bony prominences at risk of pressure damage
4. Patients are unable or do not wish to consent to participation in the trial
5. Patients are currently in another study evaluating treatments for their leg ulcer
6. Known allergy to any trial product
7. Patient has previously been in this trial
8. People with diabetes mellitus whose blood sugar not well controlled (HbA1c greater than 10% taken within the last three months). (Patients with well controlled diabetes HbA1c less than or equal to 10% are eligible for the trial)

Date of first enrolment
01/05/2009

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
United Kingdom
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Sponsor information

Organisation
University of York (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2014		Yes	No
Results article	results	01/09/2014		Yes	No
Results article	results	11/08/2015		Yes	No