ISRCTN21175670 https://doi.org/10.1186/ISRCTN21175670

VenUS III: Ultrasound for venous leg ulcers

Submission date 06/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/06/2005	**Overall study status** Completed	
Last Edited 21/07/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 02/37/03

Study information

Scientific Title

Acronym
VenUS III

Study objectives
Low dose ultrasound will accelerate the healing of 'hard to heal' venous leg ulcers used in addition to compression bandaging

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 21 August 2008: Favourable ethics review provided by York Research Ethics Committee (UK) on 04/02/2005 (Ref 05/Q1108/3).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
Low dose ultrasound administered weekly for 12 weeks, for between 5 and 10 minutes using in conjunction with compression therapy versus compression therapy alone.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Time to complete healing of all ulcers.

Key secondary outcome(s)
1. Proportion of patients with all ulcers healed at 24 weeks
2. Costs of healing ulcers
3. Health related quality of life
4. 12 month recurrence rate

Completion date
30/10/2009

Eligibility

Key inclusion criteria
People with venous ulcers treated in community or hospital out-patients with venous ulcers defined as hard to heal based on their being larger than 5 cm^2 or of greater than 6 months

duration (or both).
Able and willing to give informed written consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Active infection in the ulcer, presence of shrapnel or joint replacements near ulcerated area; allergy to ultrasound transmission gel.

Date of first enrolment
01/05/2005

Date of final enrolment
30/10/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Healthcare
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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	01/05/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	08/03/2011		Yes	No
Protocol article	protocol	01/01/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes