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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

Study website
http://www.venus3.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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 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 measure
Time to complete healing of all ulcers.

Secondary outcome measures
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

Overall study start date
01/05/2005

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

Age group
Adult

Sex
Both

Target number of participants
336

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

England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

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

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?
Protocol article	protocol	01/01/2006		Yes	No
Results article	results	01/05/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	08/03/2011		Yes	No