

Ultrasonic assisted debridement in venous leg ulcer: A randomised controlled trial

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/08/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013154714

Study information

Scientific Title

Ultrasonic assisted debridement in venous leg ulcer: A randomised controlled trial

Study objectives

Utilizing ultrasound to debride chronic leg ulcer. Will this improve chronic leg ulcer healing and avoid a possible painful sharp debridement?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Venous ulcers

Interventions

This is a randomised controlled trial comparing conventional compression bandage regime alone and with the addition of a maximum of 3 sessions of ultrasonic treatment before applying the compression bandages. Suitable patients will be recruited and matched to a control. Assessment will be taken at different intervals up to one year to detect any difference.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Ulcer sizes, complete or incomplete healing.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2004

Completion date

01/05/2005

Eligibility

Key inclusion criteria

200 patients who suffer from venous leg ulcer will be recruited from the ulcer clinic.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/05/2004

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' NHS Foundation Trust

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local 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