Ultrasonic assisted debridement in venous legulcer: A randomised controlled trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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 a different interval up to one year to detect any difference.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Ulcer sizes, complete or incomplete healing.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre Guy's and St Thomas' NHS Foundation Trust

London United Kingdom SE1 7EH

Sponsor information

Organisation

Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration