

A study to investigate the Effect of Surgery and Compression on Healing And Recurrence in chronic venous ulceration

Submission date 28/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/06/2007	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

00PRT/6

Study information

Scientific Title

Acronym

ESCHAR

Study hypothesis

The surgical correction of superficial venous surgery in addition to compression reduces venous ulcer recurrence in comparison to compression therapy alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from Gloucestershire Local Research Ethics Committee on the 29th January 1998 (ref: 98/44E).

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

Condition

Chronic venous ulceration

Interventions

Two groups were randomised to either compression therapy alone or compression plus superficial venous surgery.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Ulcer healing
2. Ulcer recurrence

Secondary outcome measures

Ulcer free time

Overall study start date

01/01/1999

Overall study end date

01/08/2002

Eligibility

Participant inclusion criteria

Open or recently healed leg ulceration (within six months) of greater than four weeks duration between knee and malleoli, with Ankle Brachial Pressure Index (ABPI) above 0.85 and duplex evidence of superficial with or without deep venous reflux.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

500

Participant exclusion criteria

1. Duplex imaging not possible
2. Patient unable/unwilling to give informed consent
3. Deep venous occlusion
4. Unfit for surgery (even under local anaesthetic)
5. Multilayer compression therapy not practical
6. Malignant ulceration

Recruitment start date

01/01/1999

Recruitment end date

01/08/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Vascular Surgery
Cheltenham
United Kingdom
GL53 7AN

Sponsor information

Organisation
South West NHS R&D Directorate (UK)

Sponsor details
Whiteladies Road
Bristol
United Kingdom
BS8 2PR

Sponsor type
Government

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) - interim grant

Funder Name
South West NHS R&D Directorate (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?
Results article	Results ()	05/06/2004		Yes	No
Results article	Long term results ()	14/07/2007		Yes	No