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

Submission date	Recruitment status	[_] Prospectively registered
28/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/06/2007	Circulatory System	

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
00PRT/6

Study information

Scientific Title

Acronym
ESCHAR

Study objectives
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

Health condition(s) or problem(s) studied
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

Completion date
01/08/2002

Eligibility

Key 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

Key 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

Date of first enrolment
01/01/1999

Date of final enrolment
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