

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Keith Poskitt

### Contact details

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United Kingdom  
GL53 7AN

## 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?
<a href="#">Results article</a>	Results ()	05/06/2004		Yes	No
<a href="#">Results article</a>	Long term results ()	14/07/2007		Yes	No