

Superficial venous surgery in the treatment of venous ulcers and the prevention of recurrence

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/07/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
N0226118474

Study information

Scientific Title

Study objectives

In addition to the role of superficial venous surgery (SVS) in venous ulcer healing and recurrence, to identify patients at risk for venous ulceration and to establish a role for SVS in the prevention of venous ulceration.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Venous ulcer

Interventions

Surgery to take place within 4 weeks of randomisation.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Improvement in venous function.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2002

Completion date

30/06/2004

Eligibility

Key inclusion criteria

Patients divided into three groups:

Patients with venous ulcers attending the vascular clinic at SMUHT

Patients with venous insufficiency, and no previous ulceration

Patients with venous insufficiency, and previous ulceration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added July 2008: 32 subjects

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/2002

Date of final enrolment

30/06/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Department of Surgery
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

South Manchester University Hospitals NHS Trust (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	01/09/2005		Yes	No