

Does venous surgery improve healing and minimise recurrence of venous ulcers?

Submission date 18/10/2000	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/10/2000	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/07/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G0000328

Study information

Scientific Title

Acronym
USABLE

Study objectives

To investigate whether simple venous surgery improves the clinical and cost-effectiveness of four layer bandaging for venous ulcers in terms both healing and recurrence.

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

1. Compression bandaging plus venous surgery
2. Compression bandaging alone

Trial closed early on 15/01/03 on feasibility grounds.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Proportion of ulcers completely healed
2. Proportion of ulcers recurring
3. Ulcer healing rate
4. Quality of life
5. Costs

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/2006

Reason abandoned (if study stopped)

Feasibility grounds

Eligibility

Key inclusion criteria

Venous ulcers associated with venous abnormality (superficial vein incompetence, with or without incompetent perforators, with or without deep vein incompetence, suitable for simple surgical correction, with or without perforating vein surgery [as shown by colour duplex scanning])

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Ankle Brachial Pressure Index (ABPI) less than 0.8
2. Intolerant to compression bandaging
3. Less than six months to live
4. Deep vein occlusion surgery and compression versus compression only

Date of first enrolment

01/06/2001

Date of final enrolment

28/02/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Vascular Surgery

London

United Kingdom

W6 8RF

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)**Funder type**

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration