

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2001

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

Age group

Adult

Sex

Both

Target number of participants

1000

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

England

United Kingdom

Study participating centre

Department of Vascular Surgery

London

United Kingdom

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Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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