ISRCTN97621126 https://doi.org/10.1186/ISRCTN97621126

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

Submission date 18/10/2000	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/10/2000	**Overall study status** Stopped	
Last Edited 29/07/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Alun Davies

Contact details
Department of Vascular Surgery
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

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
W6 8RF

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
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