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A Double Blind Randomised Trial of Valve Reinforcement and Vein Removal for the Treatment of Superficial Venous Incompetence

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 28/08/2012	**Condition category** Circulatory System	

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

N0192182505

Study information

Scientific Title

Study objectives
1. The primary aim of this study is to determine whether reinforcement of the proximal long saphenous vein valve with an exovascular cuff is as effective as removal of the long saphenous vein in the treatment of symptomatic varicose veins at various time intervals. This will be assessed by looking at patients pain levels post operatively and objectively assessing levels of post procedure bruising.
2. Secondary Research Objectives: The secondary aims are to:
2.1 Identify whether the exovascular cuff is cost effective
2.2 Assess time taken to perform the procedures
2.3. See if exovascular cuff promotes early return to normal activity
2.4 Assess long term efficacy by Duplex scan at six weeks, one year, two years and five years 5. compare use of Venocuff with VNUS

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double Blind Randomised

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
Cardiovascular: Varicose veins

Interventions
There will be 2 concurrent studies: one will involve patients with bilateral primary varicose veins and one will involve patients with unilateral primary varicose veins.

Intervention arms: no interventions withheld, additional interventions - insertion of venocuff rather than high tie and stripping of LSV.

Follow up duplex assessment of lower limb various telephone interviews and photo of patients leg.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Visual analogue scale for pain and bruising

Secondary outcome measures
Duplex ultrasound assessment of lower limb venous system competency

Overall study start date
30/06/2006

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Bilateral or unilateral primary varicose veins
2. Mild to moderate varicose veins
3. Agree to participate in study

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
1. Recurrent varicose veins
2. Thrombophlebitus affecting the LSV or tributaries
3. The ultrasonic finding of an LSV that is very dilated >10mm in female and > 11mm in male
4. Damaged thickened non mobile or absent terminal subterminal LSV values
5. Gross tortuasity along the course of the LSV
6. An inability to render the SFJ competent at operation

Date of first enrolment
30/06/2006

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Nottingham University Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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