

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
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 28/08/2012	Condition category Circulatory System	☐ Individual participant data ☐ 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
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

Primary study design

Interventional

Study design

Double Blind Randomised

Study type(s)

Treatment

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(s)

Visual analogue scale for pain and bruising

Key secondary outcome(s)

Duplex ultrasound assessment of lower limb venous system competency

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Recurrent varicose veins
2. Thrombophlebitis 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 tortuosity 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**

United Kingdom

England

Study participating centre

University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Nottingham University Hospitals NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration