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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Stephen Goode

Contact details

University Hospital
NHS Trust
B Floor, West Block, Academic Radiology
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 0115 8231176

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

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