

EVLT for Sapheno-Popliteal incompetence and SS Reflux: A RCT

| | | |
|--|---|---|
| Submission date 29/09/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/09/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/11/2011 | Condition category Surgery | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Anthony Mekako

Contact details
Alderson House
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084174061

Study information

Scientific Title

Study objectives

Is Endo Venous Laser Therapy (EVLT) superior to conventional surgery for Short Saphenous system varicose veins?

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)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Surgery: Short saphenous system varicose veins

Interventions

Data will be collected using an IBM computer and a specifically designed Microsoft Access database. The primary outcome measure will be compared between the groups by a chi-square test with continuity correction. Quality of life measures at each time point will be compared between the groups by an analysis of covariance, adjusting for the corresponding baseline values. Statistical advice will be sought from Dr Eric Gardiner, statistical consultant, who holds an honorary contract with the Hull and East Yorkshire Hospitals Trust. Health Economic advice regarding cost effectiveness / benefit analysis will be sought from the Centre of Health Economics, the University of York.

Randomisation will be carried out using envelopes method.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Residual SPJ incompetence on Duplex ultrasound

Secondary outcome measures

Not provided at time of registration

Overall study start date

15/09/2005

Completion date

01/09/2007

Eligibility

Key inclusion criteria

1. C2-C5 graded varicose veins
2. Patients that have demonstrated to have isolated SPJ incompetence and/or SSV reflux on Duplex scan
3. Patients in whom the most appropriate treatment is surgery (opinion of the patient/surgeon)
5. Patients able to give informed written consent

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

106

Key exclusion criteria

1. Patients whose varicose veins will be conservatively managed
2. Inability to give informed written consent
3. Symptomatic varicose veins which on venous duplex are not attributable to SPJ incompetence and SSV reflux
4. Evidence of deep venous reflux on duplex scan
5. Patients on anticoagulants

Date of first enrolment

15/09/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Alderson House

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 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

The North and South Bank Research and Development Consortium (UK)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/07/2006 | | Yes | No |