

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

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/11/2011	Condition category Surgery	☐ Individual participant data

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Residual SPJ incompetence on Duplex ultrasound

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Alderson House

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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