

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

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

**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?
<a href="#">Results article</a>	results	01/07/2006		Yes	No