

RCT comparing modified EVLT (endovenous laser treatment) techniques with standard EVLT technique

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/05/2008	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
N0436169958

Study information

Scientific Title

Study objectives

Modifications of laser technique might result better clinical outcome in the treatment of varicose veins due to sapheno-femoral and long saphenous incompetence. This study is designed to answer 2 questions:

1. Do these modifications result in improved symptom relief and cosmetic appearance after treatment of varicose veins?
2. Does one of these techniques reduce the total number of follow up sclerotherapy sessions needed to complete the treatment of 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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular: Varicose veins

Interventions

2 different types of modified EVLT (endovenous laser treatment) techniques vs standard EVLT technique.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. The total number of follow up sclerotherapy sessions required to complete the treatment.
2. Technical success: determined by duplex ultrasound of LSV:
 - 2.1 Successful: occlusion and non compressibility of the LSV without blood flow throughout the treated length
 - 2.2 Partial response: segmental occlusion of LSV and abolition of distal reflux
 - 2.3 Failure: reflux in treated LSV any time after treatment
3. Improvement in symptoms, using the Aberdeen Vein Questionnaire, a previously validated disease-specific quality of life instrument
4. Review and quantification of varicosities on post-EVLT photographs both prior to and after completion of sclerotherapy

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2007

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Vascular Surgical Unit

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008		Yes	No