

Is laser treatment or surgery the best way of treating varicose veins?

Submission date 11/06/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/03/2008	Condition category Circulatory System	☐ 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
VS03/2281

Study information

Scientific Title

Study objectives

Endovenous laser ablation (EVLA) produces comparable short-term results to surgery (abolition of great saphenous vein [GSV] reflux and improvement in symptoms) for the treatment of primary varicose veins due to sapheno-femoral incompetence with greater saphenous vein reflux.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from Leeds (West) Research Ethics Committee in May 2003 (ref: 03/052).

Primary study design

Interventional

Study design

Parallel group, non-blinded, randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Varicose veins

Interventions

Endovenous laser treatment (810 nm diode laser, Diomed) versus sapheno-femoral ligation, greater saphenous vein stripping and avulsions (surgery).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Abolition of GSV reflux at three months (duplex ultrasound)
2. Improvement in disease-specific quality of life (Aberdeen Varicose Vein Questionnaire)

Key secondary outcome(s)

1. Time to return to work and to normal activity
2. Pain and analgesia use during first week following treatment
3. Overall satisfaction and satisfaction with cosmetic outcome
4. Generic quality of life (36-item Short Form health survey [SF-36]) at 1 and 12 weeks following treatment
5. Complications

Completion date

01/12/2006

Eligibility

Key inclusion criteria

1. Symptomatic varicose veins
2. Primary sapheno-femoral incompetence with greater saphenous vein reflux

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unable to consent
2. Children (under 18 years)
3. Unfit for general anaesthesia
4. Recurrent varicose veins
5. Patients on long-term anticoagulation
6. Patients with anterior thigh branch of greater saphenous vein arising within 10 cm of groin and competent GSV distal to this

Date of first enrolment

05/06/2003

Date of final enrolment

01/12/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Leeds Vascular Institute

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust (UK)

ROR

<https://ror.org/00v4dac24>

Funder(s)**Funder type**

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

Diomed Ltd (UK) - part of research fellow salary paid (£15,000 pa)

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	01/03/2008		Yes	No