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

Submission date	Recruitment status	[_] Prospectively registered
11/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/03/2008	Circulatory System	

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
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).

Study design
Parallel group, non-blinded, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures

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

Overall study start date
05/06/2003

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

Age group
Adult

Sex
Both

Target number of participants
342

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
England

United Kingdom

Study participating centre
Leeds Vascular Institute
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Leeds Vascular Institute
The General Infirmary at Leeds
Great George Street
Leeds
England
United Kingdom
LS1 3EX

Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

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

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	01/03/2008		Yes	No