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Randomised controlled trial of standard EndoVenous Laser Ablation (EVLA) versus standard EVLA with below-knee foam sclerotherapy versus above and below-knee EVLA for varicose veins

Submission date 05/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/07/2007	**Overall study status** Completed	
Last Edited 05/05/2011	**Condition category** 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
N/A

Study information

Scientific Title

Acronym
Leeds EVLA technique trial

Study objectives
Modified techniques reduces requirement of delayed foam sclerotherapy and provides better clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (West) research ethics committee, at Leeds General Infirmary on 21/09/2005 (ref: 05 /Q1205/187)

Study design
Randomised controlled trial (not blinded)

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
Two modified techniques are compared with standard EVLA technique:
Group A: the standard practice of EVLA (laser ablation of above-knee Great Saphenous Vein [GSV]) considered as control

Group B: modification 1 - where GSV was ablated (EVLA) both above and below knee
Group C: modification 2 - where above knee GSV was ablated by EVLA and below knee GSV was chemically ablated using foam sclerotherapy at the same time

Group 1 - standard EVLA alone:
This uses an 810 nm bare-tipped, pulsed laser (Diomed Inc.) at a power of 12 watts. The standard technique for EVLA will be used employing a laser density of 5 pulse/cm. Delayed foam sclerotherapy up to 5 ml of 0.2-1% STD was used as required at the follow up clinic visit/s.

Group 2 - standard EVLA and on table foam sclerotherapy:
The same EVLA technique as for group 1 was used except that the GSV was cannulated below-knee (mid-calf) and a 70 cm sheath inserted. The GSV was ablated (EVLA) to the level of the knee joint following which 5 ml 1% STD (2 ml 1% STD, 3 ml air) will be injected into the below knee GSV via the sheath as it was withdrawn. Delayed foam sclerotherapy up to 5 ml of 0.2-1% STD was also be used as required at the follow up clinic visit/s.

Group 3 - above and below-knee EVLA:
The GSV was canulated below-knee (mid-calf) and the whole length of the GSV ablated using the standard EVLA technique. Delayed foam sclerotherapy up to 5 ml of 0.2-1% STD was also used as required at the follow up clinic visit/s.

Following this primary treatment patients were followed up at 1, 6, and 12 weeks and following data were obtained at each visit:
1. At 1 week:
1.1. Daily Visual Analogue Score for pain
1.2. Analgesia diary
1.3. Time to normal activity - time to return to work
1.4. Assessment of post-treatment complications
1.5. Duplex assessment of GSV and deep veins for evidence of Deep Vein Thrombosis (DVT)
2. At 6 weeks:
2.1. Outstanding data from week 1
2.2. Aberdeen Vein Questionnaire (disease-specific quality of life measure)***
2.3. Late complications
2.4. Time of return to work if greater than 1 week
2.5. Injection sclerotherapy as required in all patients
2.6. Duplex assessment of GSV
3. At 12 weeks:
3.1. Any outstanding data (as above)
3.2. Duplex Ultrasound Assessment
3.3. Aberdeen Vein Questionnaire (disease-specific quality of life measure)***
3.4. EuroQol questionnaire
3.5. Patient satisfaction
3.6. Number of sessions of injection Sclerotherapy as required***
3.7. Duplex assessment

*** = Primary endpoint measurements

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Sclerotherapy requirement at follow up: disease specific quality of life improvement measured by Aberdeen varicose vein severity score.

Secondary outcome measures
1. Post-procedure pain: patient analgesia diary
2. Cosmesis: as scored by the patient
3. Complication rates: wound infection, haematoma, nerve injury, DVT
4. Patient satisfaction

Overall study start date
10/11/2005

Completion date
15/05/2007

Eligibility

Key inclusion criteria
Patients with primary varicose veins in the leg due to isolated incompetent sapheno-femoral junction and great saphenous vein reflux both above and below knee segments.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
69 participants

Key exclusion criteria
1. Recurrent varicose veins
2. Patients with reflux in other axial veins
3. Patients with varicose veins only in thigh
4. Patients who has no reflux in below-knee segment of great saphenous vein

Date of first enrolment
10/11/2005

Date of final enrolment
15/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Leeds Vascular Institute
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

ROR
https://ror.org/04hrjej96

Funder(s)

Funder type
Research organisation

Funder Name
Leeds Vascular Institute (UK) - Research Fund

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	01/07/2008		Yes	No