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Endovenous laser therapy (EVLT) versus ultrasound-guided foam sclerotherapy (UGFS) for the treatment of varicose veins

Submission date 21/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/02/2010	**Overall study status** Completed	
Last Edited 04/03/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Varicose veins are swollen and enlarged veins that usually occur on the legs. The aim of this study is to compare two treatments for varicose veins: endovenous laser therapy and ultrasound-guided foam sclerotherapy. Endovenous laser therapy involves having a tiny laser inserted into the vein, which delivers bursts of energy that heat up the vein and seal it closed. Ultrasound-guided foam sclerotherapy involves injecting special foam into the vein, which seals it closed.

Who can participate?
Patients aged 18 or over with varicose veins

What does the study involve?
Participants are randomly allocated to be treated with either endovenous laser therapy or ultrasound-guided foam sclerotherapy. Participants are followed up for 5 years to assess their recovery, quality of life, pain and the costs of treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Ealing Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2009 to May 2016

Who is funding the study?
1. Ealing Hospital NHS Trust (UK)
2. STD Pharmaceuticals Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08/H0710/78

Study information

Scientific Title
Randomised controlled trial of endovenous laser therapy (EVLT) versus ultrasound-guided foam sclerotherapy (UGFS) for the treatment of varicose veins

Study objectives
Patient recovery, quality of life, post-procedural pain and the direct medical costs of treatment are significantly different between endovenous laser therapy (EVLT) and ultrasound guided foam sclerotherapy (UGFS).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ealing and West London Research Ethics Committee, 17/03/2009

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic venous insufficiency

Interventions
Group 1: UGFS to the long saphenous vein
Group 2: EVLT to the long saphenous vein and concurrent local anaesthetic phlebectomies

Total duration of treatment ranges from the primary procedure (1 day) to two further optional sessions, 6 weeks apart (3 months). Total duration of follow-up is 3 months after the last treatment session.

Updated 17/06/2014: Follow-up has been extended to 5 years after the last treatment session.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Return to normal activities
2. Quality of life using the Aberdeen Varicose Vein Questionnaire

All outcomes will be assessed prior to the procedure (Day 0), at 3 weeks, then after optional adjuvant UGFS sessions and finally after a further 3 months. Air plethysmography will only be carried out before treatment and 3 months after the last treatment session.

Updated 17/06/2014: Outcomes will be assessed and air plethysmography will be carried out at 5 years after the last treatment session.

Secondary outcome measures
1. Direct medical costs
2. Number of treatment sessions

3. Incidence of side-effects and complications
4. Effectiveness of treatment using duplex and air plethysmography
5. Post-procedural pain scores using a visual analogue scale
6. Change in clinical severity using the venous clinical severity scoring system

All outcomes will be assessed prior to the procedure (Day 0), at 3 weeks, then after optional adjuvant UGFS sessions and finally after a further 3 months. Air plethysmography will only be carried out before treatment and 3 months after the last treatment session.

Updated 17/06/2014: Outcomes will be assessed and air plethysmography will be carried out at 5 years after the last treatment session.

Overall study start date
01/04/2009

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years or over, either sex) with symptomatic primary varicose veins in the long saphenous distribution and reflux greater than 1 second on duplex scanning
2. Suitability for both techniques, foam and laser

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Saphenopopliteal junction incompetence
2. Previous surgery for varicose veins
3. Previous sclerotherapy for varicose veins
4. Deep vein thrombosis, previous or current
5. Significant arterial disease (Ankle Brachial Pressure Index [ABPI] less than 0.8)
6. Active malignancy
7. Coagulopathy
8. Pregnancy
9. Known allergies to local anaesthetics or sclerosants

Date of first enrolment
01/04/2009

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ealing Hospital
Middlesex
United Kingdom
UB1 3HW

Sponsor information

Organisation
Ealing Hospital NHS Trust (UK)

Sponsor details
Research and Development Office
Pasteur Suite, 8th Floor
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Sponsor type
Hospital/treatment centre

Website
http://www.ealinghospital.nhs.uk/

ROR
https://ror.org/0380w8h49

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ealing Hospital NHS Trust (UK) - Research and Development Department

Funder Name
STD Pharmaceuticals Ltd (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?
Results article	results	01/05/2012		Yes	No
Results article	results	01/08/2013		Yes	No