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

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 14/05/2008	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2005

Completion date
01/10/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
207 - Each study group comprise 69 (follow-up completed) patients. Group 1 (standard EVLT) is the control group and will be of the same size as group 2 and 3.

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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