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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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