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Randomised clinical trial comparing endovenous laser ablation with cryostripping for varicose veins: two-year results

Submission date 14/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2008	**Overall study status** Completed	
Last Edited 24/02/2009	**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

Study objectives
Study questions:
1. Is endovenous laser of the great saphenous vein clinically better than cryostripping?
2. Is endovenous laser of the great saphenous vein less expensive than cryostripping?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Regional Ethics Committee of the Mesos Medical Centre on the 15th March 2003.

Study design
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 versus cryostripping.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following were assessed at 6, 12 and 24 months:
1. Freedom from recurrence
2. Improvement in Venous Clinical Severity Score (VCSS)

3. Improvement in Aberdeen Varicose Vein Severity Score (AVVSS)
4. Improvement in the short form 6D (SF-6D), a single preference based measure of health, representing overall quality of life derived from the 36-item short form 36 (SF-36) questionnaires

Secondary outcome measures
The following were assessed at 6, 12 and 24 months:
1. Operative time
2. Complications
3. Activity impairment
4. Quality-adjusted life years (QALY)
4. Patient satisfaction

Overall study start date
01/06/2003

Completion date
01/07/2005

Eligibility

Key inclusion criteria
1. Patients with primary symptomatic varicose veins
2. Clinical, aetiological, anatomical, pathological elements (CEAP) clinical class C2 venous disease
3. Informed written consent
4. Age 19 - 75 years
5. Great saphenous vein (GSV) incompetence from the groin to below the knee, defined as retrograde flow lasting longer than 0.5 seconds on duplex ultrasound imaging

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Previous venous surgery
2. History of deep vein thrombosis (DVT)
3. C3-6 CEAP
4. Deep vein reflux
5. Anatomical duplication
6. Reflux in below-knee perforator veins

Date of first enrolment
01/06/2003

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Burg s'Jacoblaan 56
Bussum
Netherlands
1401 BS

Sponsor information

Organisation
The Mesos Medical Centre (Mesos Medisch Centrum Utrecht) (Netherlands)

Sponsor details
c/o Mr Ben Disselhoff
Van Heuven Goedhartlaan 1
CE Utrecht
Netherlands
3527

Sponsor type
Hospital/treatment centre

Website
http://www.mesos.nl

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Mesos Medical Centre (Netherlands)

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	01/10/2008		Yes	No
Other publications	reuslts on cost-effectiveness	01/03/2009		Yes	No