

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Varicose veins

Interventions

Endovenous laser versus cryostripping.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Mesos Medical Centre (Netherlands)

Results and Publications

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