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Randomised clinical trial comparing endovenous laser ablation of the great saphenous vein with and without ligation of the saphenofemoral junction, with a two-year follow-up

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 11/07/2011	**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
Is high ligation after endovenous laser ablation better than endovenous laser alone?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Regional Ethics Committee of the Mesos Medical Centre, Utrecht (The Netherlands) 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
Forty-three symptomatic patients with bilateral varicose veins were studied in which one side was randomly assigned to receive endovenous laser without saphenofemoral junction (SFJ) ligation, whereas the other side received endovenous laser with SFJ ligation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Freedom from recurrent varicose veins in the groin, as confirmed by duplex ultrasound, two years after treatment.

Secondary outcome measures
The following were assessed at 6, 12 and 24 months:
1. Abolition of reflux in the GSV
2. Venous Clinical Severity Score (VCSS)
3. Freedom from overall recurrent varicose veins
4. Procedural complications, including pain, bruising, saphenous nerve paraesthesia, tightness, superficial thrombophlebitis, skin burns, thrombotic events, and wounds

Overall study start date
01/03/2003

Completion date
01/04/2005

Eligibility

Key inclusion criteria
1. Patients with primary symptomatic bilateral varicose veins
2. Clinical, aetiological, anatomical, pathological elements (CEAP) clinical class C2 venous disease
3. Informed written consent
4. Aged 20 - 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 scanning

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
43

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

Date of first enrolment
01/03/2003

Date of final enrolment
01/04/2005

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) (The Netherlands)

Sponsor details
c/o Mr Ben Disselhoff
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1401 BS

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Mesos Medical Centre (Mesos Medisch Centrum) (The 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	01/12/2008		Yes	No
Results article	results	01/05/2011		Yes	No