

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
Registration date 31/03/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/07/2011	Condition category Circulatory System	☐ 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

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

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 venous disease
4. Deep vein reflux
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)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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