

Endovenous laser ablation (EVLA), radio frequency (RF), foam sclerotherapy and stripping for treatment of varicose veins

Submission date 31/07/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/08/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/07/2019	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

Protocol serial number
02

Study information

Scientific Title
A randomised controlled trial of endovenous laser ablation (EVLA), radio frequency (RF), foam sclerotherapy and stripping for treatment of varicose veins

Acronym

SOL

Study objectives

Endovenous laser ablation (EVLA), radio frequency (RF), foam sclerotherapy and stripping for the treatment of varicose veins all have equal outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethics committee approved of this trial prior to first patient enrolment.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Varicose veins

Interventions

1. Surgery: high ligation and stripping plus stab phlebectomies
2. Endovenous laser ablation plus phlebectomies
3. Radiofrequency ablation plus phlebectomies
4. Ultrasound guided foam sclerotherapy plus phlebectomies

Duration of treatments: 1 hour

Duration of follow up: 5 years

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Recurrent varicose veins after surgery (REVAS), measured at baseline, 1 month, 12 months, yearly thereafter for a total of 5 years.

Key secondary outcome(s)

Measured at baseline, 1 month, 12 months, yearly thereafter for a total of 5 years:

1. Quality of life
2. Varicose vein severity score (VVSS)

Completion date

01/01/2012

Eligibility

Key inclusion criteria

1. Varicose veins due to greater saphenous vein (GSV) insufficiency
2. Aged greater than or equal to 18 years, to an upper limit of 75 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

500

Key exclusion criteria

Aged below 18 and above 75 years

Date of first enrolment

01/01/2007

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Denmark

Study participating centre

Eskadronsvej 4A

Naestved

Denmark

4700

Sponsor information

Organisation

Danish National Health Insurance (Denmark)

Funder(s)

Funder type

Government

Funder Name

Danish National Health Insurance (Denmark)

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	01/08/2011	11/07/2019	Yes	No
Results article	results	01/10/2013	11/07/2019	Yes	No