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 [X] 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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.

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

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date 01/01/2007

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

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 500

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)

Sponsor details Danske regioner

Dampfærgevej Copenhagen Denmark 5112

dr@regioner.dk

Sponsor type Government

Funder(s)

Funder type Government

Funder Name

Danish National Health Insurance (Denmark)

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