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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/08/2009	**Overall study status** Completed	
Last Edited 11/07/2019	**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
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
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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