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Comparing endovascular laser, ultrasound-guided foam sclerotherapy, and conventional surgery for the treatment of small saphenous varicose veins

Submission date 28/06/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/07/2010	**Overall study status** Completed	
Last Edited 24/06/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Small saphenous varicose veins are swollen and enlarged veins – usually blue or dark purple – that are found on the legs. The aim of this study is to compare three treatments for small saphenous varicose veins: endovenous laser treatment, ultrasound-guided foam sclerotherapy, and conventional surgery. Endovenous laser treatment involves having a catheter inserted into the affected vein; a tiny laser is passed through the catheter that delivers short bursts of energy to heat up the vein and seal it closed. Ultrasound-guided foam sclerotherapy involves injecting special foam into the affected vein, which scars the vein and seals it closed.

Who can participate?
Patients aged 18-75 with varicose veins

What does the study involve?
Participants are randomly allocated to be treated with either endovenous laser treatment, ultrasound-guided foam sclerotherapy, or conventional surgical removal of the short saphenous vein. Participants are followed up after 3 days, 1 month, 1 year, 3 years, and 5 years to assess treatment effectiveness and recurrence of the varicose veins.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Åreknudeklinikken (Denmark)

When is the study starting and how long is it expected to run for?
September 2010 to September 2020

Who is funding the study?
Foundation of the National Health Security System (Fonden for faglig udvikling af speciallægepraksis) (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
26141788A

Study information

Scientific Title
A three-arm, parallel group, randomised controlled trial of patients with small saphenous vein insufficiency treated with either endovascular laser, ultrasound-guided foam sclerotherapy, or conventional surgery

Study objectives
Successful treatment of small saphenous varicose veins using laser, foam or surgery is equally possible, and will give a successful removal of insufficiency in 90% of patients treated.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The local Danish ethics committee approved in April 2010

Study design
Multicentre three-arm randomised controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Small Saphenous vein varicose veins

Interventions
330 patients will be randomised to receive either:
1. Endovenous laser destruction of the short saphenous vein
2. Ultrasound-guided foam sclerotherapy of the short saphenous vein
3. Conventional surgical removal of the short saphenous vein

Follow up after 3 days, 1 month, 1 year, 3 years, and 5 years thereafter.

Intervention Type
Procedure/Surgery

Primary outcome measure
Amended as of 12/11/2010 to following:
1. Efficacy
2. Recurrent varicose veins

Initial information at time of registration:
1. Interruption of sensitivity and motor skills
2. Reflux equivalent to the inlet of Parva, more than 1,5cm from the inlet and distally equivalent to the treated part of Parva
3. Reflux equivalent to new vessels/perforants in the fossa poplitea
4. New varicose veins
5. Return to normal activities
6. Return to work
7. Use of pain tablets
8. Pain score (analogue scale 0-10), daily for the first 10 days
9. Additional venous treatments on the treated leg

Secondary outcome measures
Amended as of 12/11/2010 to following:
1. Interruption of sensitivity and motor skills
2. Reflux equivalent to the inlet of Parva, more than 1.5 cm from the inlet and distally equivalent to the treated part of Parva
3. Reflux equivalent to new vessels/perforants in the fossa poplitea
4. New varicose veins
5. Return to normal activities
6. Return to work
7. Use of pain tablets
8. Pain score (analogue scale 0 - 10), daily for the first 10 days
9. Additional venous treatments on the treated leg

Initial information at time of registration:
1. Intervention time from "skin to skin"
2. Number of phlebectomies
3. Small saphenous vein diameter 5 cm distal from the saphenopopliteal inlet
4. Aberdeen varicose veins symptoms severity score (AVVSS)
5. SF - 36 quality of life questionnaire
6. Venous severity score
7. Venous procedures on the treated leg

Overall study start date
01/09/2010

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Age: 18-75
2. Informed approval
3. Varicose veins with symptoms, and reflux in Small Saphenous Vein defined as 0,5 seconds reflux after manual compression of the calf while standing
4. Clinical, Etiologic, Anatomic and Pathophysiologic (CEAP) classification C2-C4
5. Bilateral treatment is allowed when the same treatment is given to both legs during the same intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Deep Venous Thrombosis (DVT) of the leg
2. Insufficient popliteal perforants
3. Previous varicose surgery in the popliteal area
4. Age under 18
5. Contradictions against use of Aethoxysklerol®
6. Great saphenous vein insuffienciency at the same time or surgery for Great Saphenous vein insufficiency < 3 months previously
7. History or foot-pulse indicating arterial insufficiency or/and ankle/arm index <0.9
8. Convoluted or disrupted Parva, that will make it inappropriate for the treatments
9. Other anatomical relations that will make surgery difficult
10. Pregnant or have given birth < 3 months previously

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
Denmark

Sweden

Study participating centre
Nordre Kystagervej 28
Hviovre
Denmark
2650

Sponsor information

Organisation
Åreknudeklinikken (Denmark)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Foundation of the National Health Security System (Fonden for faglig udvikling af speciallægepraksis) (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