

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

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<b>Registration date</b> 08/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/06/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?

Dr Lars H. Rasmussen  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Lars H. Rasmussen

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**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 insufficiency at the same time or surgery for Great Saphenous vein insufficiency < 3 months previously

7. History of 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)

## Funder(s)

**Funder type**

Government

**Funder Name**

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

## Results and Publications

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration