

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

<b>Submission date</b> 31/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	01/08/2011	11/07/2019	Yes	No
<a href="#">Results article</a>	results	01/10/2013	11/07/2019	Yes	No