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# FOAM-study veins: cost minimisation study comparing surgery versus duplex guided foam sclerotherapy of varicose veins - a randomised controlled study

**Submission date**
07/06/2006

**Registration date**
07/06/2006

**Last Edited**
17/09/2008

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
NTR654

## Study information

### Scientific Title

### Study objectives
The underlining hypothesis of this study is that duplex guided foam sclerotherapy may save costs and be more acceptable for patients than ligation and stripping of the greater saphenous vein, because there is no need for anaesthesia and incisions and it lacks several side-effects, such as scars, haematomas and a painful recovery period of at least 7 days known after surgical intervention.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the local medical ethics committee

### Primary study design
Interventional

### Study design
Multicentre, randomised, active controlled, parallel group trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Varicose veins

### Interventions
1. Standardised duplex guided foam sclerotherapy
2. Standardised surgery procedure

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Cumulative probability of recurrent varicose vein at 18 - 24 months after treatment.

### Key secondary outcome(s)
1. Quality of life (EuroQol-5D)
2. Patient preference
3. Social costs

### Completion date
01/03/2009

## Eligibility

### Key inclusion criteria
1. Primary truncal varicosities of the greater saphenous vein (GSV)
2. Aged greater than 18 years
3. Reflux greater than 0.5 seconds and insufficiency of the sapheno-femoral (SF) junction measured by duplex
4. Reflux for at least 20 cm of the GSV in the upper leg
5. Informed consent
6. Normal deep venous system

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Signs of deep vein thrombosis (DVT) found with duplex
2. Immobility
3. Allergy for polidocanol in the past
4. Life-expectancy less than 3 years
5. Pregnancy
6. Abnormal deep venous system
7. Active ulcus cruris

### Date of first enrolment
01/02/2006

### Date of final enrolment
01/03/2009

## Locations

### Countries of recruitment
Netherlands

### Study participating centre

**Academic Hospital Maastricht (AZM)**
Maastricht
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# Sponsor information

**Organisation**
Academic Hospital Maastricht (AZM) (The Netherlands)

**ROR**
https://ror.org/02d9ce178

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

# Results and Publications

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

**IPD sharing plan summary**
Not provided at time of registration