

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/09/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Cumulative probability of recurrent varicose vein at 18 - 24 months after treatment.

Secondary outcome measures

1. Quality of life (EuroQol-5D)
2. Patient preference
3. Social costs

Overall study start date

01/02/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

460

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 ulcer 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

Netherlands

6202 AZ

Sponsor information

Organisation

Academic Hospital Maastricht (AZM) (The Netherlands)

Sponsor details

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Sponsor type

University/education

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

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