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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

Recruitment status
No longer recruiting

Registration date
07/06/2006

Overall study status
Completed

Last Edited
17/09/2008

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

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 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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6202 AZ

Sponsor information

Organisation
Academic Hospital Maastricht (AZM) (The Netherlands)

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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