FOAM-study veins.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26519

Source
NTR

Brief title
N/A

Health condition

Primary varicose veins due to greater saphenous vein insufficiency

Sponsors and support

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

Varicose veins in the legs is a common health problem. Ten percent of the population needs medical intervention. It causes high health care costs.Nowadays treatment modalities include surgery and duplex guided foam sclerothrapy. Both treatments are equally effective in terms of recurrences, however some studies indicate superiority of surgery and other studies indicating superiority of scelrotherapy. Costs associated with both treatments and patient preferences have never been studied. There is a need for a well-designed study comparing the effectiveness, the costs and patient acceptability and minimizing costs. The hypothesis underlying this study is that duplex guided foam sclerotherapy may be cost saving and is more acceptable for patients, because there is no need for anaesthesia and incisions and it is without side-effects, such as scars, haemotomas and a painful recovery period of at least 7 days. We designed a randomized controlled trial, the number of patients needed per group is estimated to be n=230. The primary outcome measure is the cumulative probability of recurrent varicose vein within 24 months after treatment. Secondary outcome measures are quality of life(as measured by EuroQol-5D), patient preferences(as measured by cojoint analysis) and costs. Cost-minimization analysis with potentially cost savings of 339.328 euros per year for the adherence(=target) population of the University Hospital of Maastricht. The study will take approximately 36 months in total.

Study objective

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

Intervention

1. Standardized duplex guided foam sclerotherapy;
2. Standardized surgery procedure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary trunkal varicositas of the GSV;
2. Age > 18 years;
3. Reflux>0.5 s and insufficiency of the 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.

Exclusion criteria

1. Signs of DVT found with duplex;
2. Immobility;
3. Allergy for polidocanol in the past;
4. Life-expectation < 3 years;
5. Pregnancy;
6. Abnormal Deep Venous System;
7. Active ulcus cruris.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2006
Enrollment:	460
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-01-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL598
NTR-old	NTR654
Other	: N/A
ISRCTN	ISRCTN74375188

Study results

Summary results

N/A