Parva II Trial: Randomized unicentre trial of re-crossectomy vs (repeated) ultrasound guided foam sclerotherapy of recurrence after crossectomy of the small saphenous vein

Published: 03-03-2009
Last updated: 06-05-2024

To compare the success rate and the occurrence of complications of re-crossectomy and (repeated) UGFS for the treatment of recurrence of the SSV for a period of 5 years.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON33660

Source
ToetsingOnline

Brief title
SSV II Trial

Condition

- Venous varices

Synonym
recurrence of varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: geen geldstroom nodig;aangezien het beide standaardbehandelingen zijn binnen de afdeling dermatologie en heelkunde

Intervention

Keyword: anatomical success, re-crossectomy, small saphenous vein, UGFS

Outcome measures

Primary outcome

Anatomical and/or hemodynamic success on ultrasound examination. Success is defined by the absence of reflux >0.5 seconds (with or without sclerus) in the SSV at 2 sites: the saphenopopliteal junction and halfway the calf (after 3, 12 months and 5 years).

Secondary outcome

1. Number of additional UGFS treatments after the randomized treatment.

2. Number and type of additional treatments for varicosities in study limb.

3. Patient's satisfaction about the treatment (10-points scale, from very unsatisfied to very content) after 3 and 12 months.

4. Quality of life, measured with the SF-36 test on t=0, after 2 weeks and after 3 months.

5. Patient's reported complications (pain, hematoma, infection, paresthesia) and doctor's reported complications after 2 weeks (superficial and deep thrombosis, hyperpigmentation).

Study description

Background summary

Complications of primary varicose veins have a great impact on patients* health related quality of life, which is comparable to other common diseases, and is associated with considerable health care costs. Treatment of varicose veins is important in prevention of complications. Crossectomy and ultrasound guided foam sclerotherapy (UGFS) are the common treatment modalities of insufficiency of the SSV. Crossectomy is a relatively difficult operation and has a high recurrence rate (50% after 5 years). Re-crossectomy of the SSV is even more difficult because the anatomy has changed and the veins are usually tortuous. Re-operation is again associated with a high risk of recurrence or failure.
UGFS is a swift and easy treatment whereby the SSV is punctured and injected with foam. With this treatment there is no need of (general or spinal) anesthesia.

Study objective

To compare the success rate and the occurrence of complications of re-crossectomy and (repeated) UGFS for the treatment of recurrence of the SSV for a period of 5 years.

Study design

Prospective randomized study of success and complications of re-crossectomy and (repeated) UGFS for treatment of recurrence (after crossectomy in the past) of the SSV.

Intervention

crossectomy vs ultrasound guided sclerofoam therapy

Study burden and risks

The treatments within the study are identical to the treatments that would be normally given to the same patient. The study only compares the effectivity and complications of the two regular treatments. The burden for the patient will be two extra visits to the hospital, 15 minutes each. Also the patients will be asked to fill in two questionairies which will take approximately 30 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Objective insufficiency (> 0.5 seconds on ultrasound examination) of the SSV after crossectomy (with or without stripping) with visible neovascularisation at the sapheno-popliteal junction

Exclusion criteria

thrombosis (superficial or deep) or thrombotic disease

Study design

Design

Study phase: 4

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Date:	03-03-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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
CCMO	NL25689.101.08