

VESPA Trial: Endovenous laser treatment versus crossectomy of the small saphenous vein.

Published: 24-07-2008

Last updated: 07-05-2024

This randomized trial will compare EVLT with saphenopopliteal ligation with regard to therapy failure (a) and recurrence (b). a. Insufficiency of the SSV determined by ultrasound 6 weeks post-treatment is regarded as a therapy failure. b....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32315

Source

ToetsingOnline

Brief title

VESPA

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym

varicose veins, venous insufficiency

Research involving

Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis

Source(s) of monetary or material Support: Ministerie van OC&W,AngioCare BV

Intervention

Keyword: crossectomy, EVLT, saphenous, small

Outcome measures

Primary outcome

Insufficiency after 6 weeks (therapyfailure).

Insufficiency after 1 year (recurrence)

Secondary outcome

Quality of life, morbidity, cosmetic results, duration of treatment, resumption of work.

Study description

Background summary

Venous insufficiency has a high incidence worldwide. It is seen in 5-15% of all men and 15-30% of all women in western countries, varying from cosmetic complaints to chronic venous insufficiency and ulcers. The prevalence of insufficiency of the small saphenous vein (SSV) is 10-18%. In the early twentieth century the surgical procedure of choice for insufficiency of the great saphenous vein (GSV) was the saphenofemoral ligation and GSV stripping. Since stripping of the SSV resulted in a large number of nerve damages of the sural nerve, the method was adjusted to the saphenopopliteal ligation. The percentage of therapy failure (persistent insufficiency of the SSV perioperatively) is 25%. Reflux at one year was seen in 52%. The number of therapy failure is explained by the variable anatomy of the SSV and its junction.

Endovenous laser treatment (EVLT) is a minimal invasive, percutaneous, endovenous technique causing heat mediated steam bubbles resulting in endothelial damage and occlusion of the venous segment. EVLT is a widely used technique for treatment of insufficiency of the GSV. The use of EVLT for treatment of the insufficiency of the SSV has not been investigated earlier by a randomized trial. Due to the fact that the SSV is cannulated under ultrasound guidance, it is certain the correct vein is being treated. This may result in a reduction of therapy failures and long term insufficiency.

Study objective

This randomized trial will compare EVLT with saphenopopliteal ligation with regard to therapy failure (a) and recurrence (b).

- a. Insufficiency of the SSV determined by ultrasound 6 weeks post-treatment is regarded as a therapy failure.
- b. Determination of insufficiency of the SSV using ultrasound after one year.

Study design

randomized multi-center trial, non blinded

Intervention

Ligation of saphenopopliteal junction versus EVLT.

Study burden and risks

The saphenopopliteal ligation is performed under spinal anaesthesia, the ELVT is performed under local anaesthesia.

Contacts

Public

Sint Franciscus Gasthuis

Kleiweg 500
3045 PM Rotterdam
NL

Scientific

Sint Franciscus Gasthuis

Kleiweg 500
3045 PM Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Insufficiency of the saphenopopliteal junction.

Exclusion criteria

Diameter of the small saphenous vein less than 2 mm.

Occlusion of the deep venous system

tortuous small saphenous vein

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2008
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date: 24-07-2008

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	NL22668.101.08