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

No registrations found.

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

Summary

ID

NL-OMON20493

Source
NTR

Brief title
N/A

Health condition

insufficienct small saphenous vein

Sponsors and support

Primary sponsor: AngioCare BV
Source(s) of monetary or material Support: AngioCare BV

Intervention

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 en 15-30% of all women in western countries, varying from cosmetic complaints to chronic venous insuffiency 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 insufficient 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

Endoveneus laser treatment op the small saphenous vein is compareble to crossectomy with

regard to recurrence and therapy failure.

Study design

Questionnaires preoperatively and at 1, 2, 6 and 12 weeks and 12 months.

Duplex at 6 weeks and 12 months.

Intervention

Endovenous laser treatment (EVLT)

Ligation of saphenopopliteal junction

Contacts

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Eligibility criteria

Inclusion criteria

1. Insufficiency of the small saphenous vein
CEAP 2 to 6

2. Age > 18 years old

3. Comprehension of the dutch language

4. Treatment of a least 10 cm

5. Informed consent

Exclusion criteria

1. Diameter less than 2 mm

2. Simultaneous insufficiency of the large saphenous vein

3. Arterial insufficiency

4. Pregnancy

5. Recurrent insufficiency of the small saphenous vein

6. Spiral shape of the small saphenous vein

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2008

Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion Date:	24-11-2008
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	NL1484
NTR-old	NTR1554
Other	TWOR : 2008/11
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A