Is wearing compressive stockings useful after Endovenous Laser Therapy (EVLT)?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19952

Source
Nationaal Trial Register

Health condition

EVLT, compressive stockings, varicosis, varicose veins.

Sponsors and support

Primary sponsor: maatschap chirurgie SFG, Rotterdam
Source(s) of monetary or material Support: maatschap chirurgie SFG, Rotterdam

Intervention

Outcome measures

Primary outcome

Quality of life, as measured with AVVQ and VCCS.

Secondary outcome

Painscore and complications, measured using a visual assisted painscore and physical examination.

Study description

Background summary

Varicose veins may cause complaints of pain, tiredness of the legs, cosmetic complaints, iching or muscle cramp in calf or feet. EndoVenous Laser Therapy (EVLT) is the treatment of choice in our hospital for insufficiency of the greater saphenous vein (GSV) where thermic ablation of the vein is effectuated under local anesthesia. After the EVLT patients nowadays arre proscribed compressive stockings for a period of time, that differs in every clinic and with every clinician. However, the need to wear these compressive stockings after EVLT has never been proven. Therefore we want to conduct a prospective randomised clinical trial, at which the the study group will not be wearing compressive stockings. The primary objective of this prospective randomised clinical trial will be quality of life, as to be measured using the Dutch Translated AVVQ. Secundary objectives will be quality of life, painscore and complications, measured using the VCSS, a visual assisted painscore and physical examination. Furthermore wil will examin the effectivity of our treatment of these varicose veins using duplex-ultrasound. After power analysis we will include 300 patients. These patients will all be treated for insufficiency of the GSV. After randomisation the studygroup will not be wearing compressive stockings, whereas the control group will be wearing compressive stockings for 2 weeks after the treatment. The follow-up is going to be one year.

Study objective

Nowadays after every venous treatment some form of compressive treatment is prescribed. Its use has been proven for surgical interventions, but is unclear for EVLT. Patients often think of wearing of these stockings as a burden.Therefore we will conduct a randomised clinical trial to define the use of wearing compressive stockings after EVLT.

Study design

T0= Outpatient clinic visit;

T1= Treatment;

T2= 2 weeks after treatment;

T3= 4-6 weeks after treatment;

T4= 1 year after treatment.

Intervention

After randomisation the studygroup will not be wearing compressive stockings, whereas the control group will be wearing compressive stockings for 2 weeks after the treatment.

Contacts

Public
Kleiweg 500
A.J. Runia
Rotterdam 3045 PM
The Netherlands
+31 (0)10 4616161
Scientific
Kleiweg 500
A.J. Runia
Rotterdam 3045 PM
The Netherlands
+31 (0)10 4616161

Eligibility criteria

Inclusion criteria

Venous insufficiency Greater Saphenous Vein (GSV), to be treated using EVLT

Exclusion criteria

1. Chronic venous insufficiency;

2. Already wearing compressive stockings;

3. Periferal arterial disease;

4. Previous treatment GSV;

5. Age < 18 yrs;

6. Insufficient understanding dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2011
Enrollment:	180
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2610
NTR-old	NTR2738

Register	ID
Other	CCMO : 32137
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A