Elastic stockings after varicose vein surgery: useful or nonsense.

No registrations found.

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

Summary

ID

NL-OMON20732

Source
Nationaal Trial Register

Brief title
ESaVS

Health condition

The standard surgical treatment for varicose veins is stripping of the greater saphenous vein. More recently minimally invasive techniques like endovenous laser therapy of the incompetent greater saphenous vein have gained increasing popularity. Post-operatively after both techniques, patients usually receive compression therapy with elastic stockings. However, no evidence is available to support this routine and frequently the patients experience discomfort from the use of these stockings.

Sponsors and support

Primary sponsor: Hulsewé
Dr.
Karel
Chirurg
Orbis Medisch Centrum
Dr. H. van der Hoffplein 1
Postbus 5500
6130 MB Sittard
Nederland
k.hulsewe@orbisconcern.nl

Source(s) of monetary or material Support: Hulsewé
Dr.
Karel
Chirurg
Orbis Medisch Centrum
Dr. H. van der Hoffplein 1
Postbus 5500
6130 MB Sittard
Nederland
k.hulsewe@orbisconcern.nl

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is the pain score. Pain will be measured using a visual analogue scale. In the first week patients will keep score of their pain daily and in the following 5 weeks they will register their pain scores weekly. We will investigate the difference between the group with and the group without elastic stockings in these parameters.

Secondary outcome

1. Presence of complications (deep venous thrombosis, haematoma, thrombophlebitis, wound-infections, oedema);

2. Time before returning to work (or hobby or sports);

3. Analgesics consumption;

4. Leg volume;

5. Functioning- and Varicose vein-scores (RAND-36, AVVQ).

Study description

Background summary

The standard surgical treatment for varicose veins is stripping of the greater saphenous vein. More recently minimally invasive techniques like endovenous laser therapy of the incompetent greater saphenous vein have gained increasing popularity. Post-operatively

after both techniques, patients usually receive compression therapy with elastic stockings. However, no evidence is available to support this routine and frequently the patients experience discomfort from the use of these stockings. Our hypothesis is that routine application of elastic stockings after varicose vein surgery is not beneficial with regard to pain- and physical functioning scores, complications, edema formation, time before returning to work and analgesics consumption.

The main objective is to determine whether the post-operative application of elastic stockings after varicose vein surgery is useful to reduce post-operative pain. Secondly we want to determine whether there is a difference in physical functioning scores, complications, leg edema, time before returning to work and analgesics consumption between wearing and not wearing elastic stockings post-operatively.
Patients can choose either surgical treatment or endovenous treatment. Then patients will be randomised to either a group who wears elastic stockings 2 weeks post-operatively or a group who does not wear elastic stockings post-operatively after the procedure.

The study population consists of patients from 18 to 65 years, both male and female, who are diagnosed with primary stem varicose veins and who will be treated with inverted stripping of the greater saphenous vein with high ligation of the saphenofemoral junction or endovenous laser therapy.

One group wears elastic stockings (class II) for two weeks post-operatively and one group does not wear elastic stockings.

The main study endpoint are the pain scores. Secondly we will assess the number of complications, functioning scores, number of re-interventions, amount of analgesics consumption, time before returning to work and leg edema.

Study objective

Our hypothesis is that routine application of elastic stockings after varicose vein surgery is not beneficial with regard to pain- and physical functioning scores, complications, edema formation, time before returning to work and analgesics consumption.

Study design

1. Pain: VAS-score in a diary: Pre-operatively, each day in the first week postoperatively, followed by a VAS-score at the end of each week up to week 6;

2. Complications: 2 days, 14 days and 6 weeks post-operatively;

3. Leg volume: pre-operatively, 2 days, 14 days and 6 weeks post-operatively;

4. Analgesics consumption in a diary. Each day for 6 weeks post-operatively;

5. Time before returning to work: on follow up at 14 days or 6 weeks;

6. RAND-36 and AVVQ: pre-operatively, 2 days, 14 days and 6 weeks post-operatively.

Intervention

Patients will receive elastic stockings (class II) up to the thigh during the day for two weeks. Stockings with a pressure gradient are used for treatment of venous insufficiency. These stockings are usually given for 2 weeks post-operatively. The open-surgically treated patients will undergo is inverted stripping of the greater saphenous vein with high ligation of the saphenofemoral junction. The endovenously treated patients will undergo is endovenous laser therapy (EVLT).
The investigational treatment is the absence of stockings in comparison to the use of stockings.

Contacts

Public
Postbus 5500
J. Elderman
Orbis Medisch Centrum,
Dr. H. van der Hoffplein 1

Sittard 6130 MB
The Netherlands
Scientific
Postbus 5500
J. Elderman
Orbis Medisch Centrum,
Dr. H. van der Hoffplein 1

Sittard 6130 MB
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age between 18 and 65 years;

2. Duplex-proven varicose veins with insufficient saphenofemoral crosse;

3. CEAP-classification: C2-4EpAs,pPr;

4. Informed consent;

5. Suitable for surgical treatment and/or endovenous laser therapy.

Exclusion criteria

1. Pregnancy;

2. Refusal of informed consent;

3. Deep venous thrombosis in medical history;

4. Previous surgery to vascular structures in lower extremities;

5. Secondary varicose veins;

6. Ulcerative lesions on lower extremities;

7. Contra-indication for use of elastic stockings.

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):	01-04-2009
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-05-2009
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	NL1718
NTR-old	NTR1828
Other	METC Atrium-Orbis-Zuyd : 09-T-03
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A