Efficacy of routine elastic stockings after varicose vein surgery: a prospective randomised trial.

Published: 19-02-2009
Last updated: 09-11-2024

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...

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

Summary

ID

NL-OMON33741

Source
ToetsingOnline

Brief title
ESaVS

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym
varicose veins, varicosis

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: postoperative compression, stockings, varicose veins

Outcome measures

Primary outcome

The main study endpoint are the pain scores.

Secondary outcome

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 description

Background summary

The standard surgical treatment for varicose veins is stripping of the greater saphenous vein. Post-operatively, 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, analgesics consumption and number of re-interventions.

Study objective

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 analgesics consumption and number of re-interventions between wearing and not wearing elastic stockings post-operatively.

Study design

Prospective randomised trial. 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 varicose vein surgery.

Intervention

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

Study burden and risks

The burden to the patients is that they have to visite the hospital one extra time beside the usual check-ups. The filling out of the questionnaires takes 15 minutes per visit. The patients* leg circumference of both legs will be measured at 3 points each visit on a non-invasive way. Patients are asked to fill out a VAS-score each day in the first day post-operatively and in the following 5 weeks weekly. Further more patients will be asked to register the amount of analgesics consumed at home in a diary during the 6 weeks period post-operatively.
The risk of the study is that patients not wearing stockings experience significantly more complications, pain or other discomfort. An interim-analysis will be carried out to prevent disadvantages to one of the study groups.

Contacts

Public
Orbis Medisch Centrum

Dr. H van der Hoffplein 1
6162 BG Sittard-Geleen
Nederland
Scientific
Orbis Medisch Centrum

Dr. H van der Hoffplein 1
6162 BG Sittard-Geleen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 18 and 65 years
- Duplex-proven varicose veins with insufficient sapheno-femoral crosse
- CEAP-classification: C1-4EpAs,pPr
- Informed consent

Exclusion criteria

- Pregnancy
- Refusal of informed consent
- Deep venous thrombosis in medical history
- Previous surgery to vascular structures in lower extremities
- Secondary varicose veins
- Ulcerative lesions on lower extremities
- Contra-indication for use of elastic stockings

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	01-04-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL26229.096.08