Considering compression after varicose vein surgery; a randomised controlled trial.

Published: 01-02-2010
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"the effects of compression bandages after varicose vein surgery".

Ethical review	Approved WMO
Status	Completed
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON32564

Source
ToetsingOnline

Brief title
Considering compression

Condition

- Venous varices

Synonym
varicose veins - varicosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: After surgery, Compression, Varicose veins

Outcome measures

Primary outcome

Postoperative edema (leg volume) and pain scores are considered primary

endpoints.

Secondary outcome

Postoperative complications and limitation of mobilisation are secundary

endpoints.

Study description

Background summary

The incidence in Dutch primary care of varicosis is 5 per 1000 patients and 18.473 strippings were performed in 2007. Surgical treatment for primary varicosis of the great saphenous vein (GSV) in the Netherlands is saphenous ligation, crossectomy and short stripping of the great saphenous vein.
After GSV stripping, compression therapy with compression bandages is prescribed to reduce haemorrhage, oedema, haematoma and pain, based on the guidelines of the Dutch Society for Surgery.There is not much evidence yet regarding the usefull length of time of compression bandages after varicose vein surgery. The effects of compression bandages after surgery for primary varicosis of the greater saphenous vein are studied.

Study objective

"the effects of compression bandages after varicose vein surgery".

Study design

RCT

Intervention

The intervention is shortening the period of compression bandaging from 72 to 4 hours after varicous vein surgery.

Study burden and risks

- higher risk on leg edema
- higher risk on leg hematoma
- higher risk on pain in the operated leg

Contacts

Public
Selecteer

Postbus 4446
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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Primary uni- or bilateral insufficiency of the greater saphenous vein

Exclusion criteria

- CEAP C6
- certain non- compliance for wearing bandaging

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-03-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	compression bandaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-02-2010
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	NL30122.096.09