

Effects of elastic stockings after varicose vein surgery

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"the effects of elastic stockings after varicose vein surgery".

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

Summary

ID

NL-OMON30410

Source

ToetsingOnline

Brief title

Condition

- Venous varices

Synonym

varicose veins

Research involving

Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum

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

Intervention

Keyword: elastic stockings, RCT, varicose vein surgery

Outcome measures

Primary outcome

Postoperative edema (leg volume), comfort (pain) and return to normal mobilisation are considered primary endpoints

Secondary outcome

Postoperative complications

Study description

Background summary

Effects of elastic stockings after varicose vein surgery

Worldwide, most patients wear elastic stockings for several weeks after surgery for varicose veins. For this, there is very little scientific evidence: in a randomised controlled trial it appeared that class I stockings (15mmHg) for one week ought to be sufficient in preventing postoperative effects like hematoma and thrombophlebitis.

The effects of wearing elastic stockings after surgery for primary varicosis of the greater saphenous vein are studied. Patients are randomised to either wearing stockings for four weeks, or none at all. Postoperative edema (leg volume), comfort (pain) and return to normal mobilisation are considered primary endpoints.

Study objective

"the effects of elastic stockings after varicose vein surgery".

Study design

RCT

Intervention

The intervention is the omission of an elastic stocking after varicose 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

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Scientific

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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 varicous Vena Saphena Magna vein

Exclusion criteria

ulcera cruris

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2007
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	elastic stockings
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
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	NL14812.096.06