A randomized controlled trial comparing 4 hours of pressure bandage after radiofrequency ablation with standard aftercare for primary great saphenous vein incompetence

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to evaluate if 4 hours of pressure bandage has the same effect as current practice (3 days of a Class II TEK stocking). The secondary objective is to study the hinder and quality of life for the patients

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

Summary

ID

NL-OMON35851

Source
ToetsingOnline

Brief title
Compression therapy after RFA for GSV incompetence

Condition

- Venous varices

Synonym
varicosis, venous incompetence

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: geen aparte financiering

Intervention

Keyword: aftercare, compression, radiofrequent ablation, VSG

Outcome measures

Primary outcome

The primary endpoint is edema of the leg, objectified by volume measurements using a Perometer® (Bösl Medizintechnik, Aachen- Deutschland) at 3 moments: pre-operative, 3 days and 2 weeks

Secondary outcome

Post-operative pain, postoperative complications, time to full recovery and quality of life are secondary endpoints. Postoperative pain will be scored by the patient on a VAS scale from 0-10. The HRQOL will be estimated by the SF-36 questionnaire, which will be asked to fill in at randomization and after 2 weeks. Included will be the question to determine time to full recovery after the operation. Postoperative complications will be documented

Study description

Background summary

In developed countries lower extremity venous insufficiency affects up to 15% of men and 35% of women [1, 2], leads to significant reduction in health-related quality of life (HRQOL) and accounts for 1-2% of the total health care spending. Radiofrequency ablation (RFA) is an accepted treatment for patients with primary GSV incompetence. However the best aftercare is not known.

Study objective

to evaluate if 4 hours of pressure bandage has the same effect as current practice (3 days of a Class II TEK stocking). The secondary objective is to study the hinder and quality of life for the patients

Study design

prospective, non-blinded, randomized, controlled, single center, intervention study

Intervention

After randomization patients will be allocated to either pressure bandage for 4 hours or a class II TEK stocking for 3 days

Study burden and risks

All patients who are randomized to the study may benefit from a shorter aftercare period or receive standard aftercareIn ontwikkelde landen

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients with primary varicosity of the GSV, between age 18-80 year (C2 * C4 according to CEAP classification)
- unilateral radiofrequency ablation

Exclusion criteria

- ulcus cruris (C6 according to CEAP classification)
- healed ulcus cruris (C5 according to CEAP classification)
- non-compliance to wearing pressure bandage
- bilateral radiofrequency ablation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2011
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	NL36341.096.11