A randomized controlled trial comparing no compression therapy versus 4 hours of compressive therapy with a TED class II stocking after radiofrequency ablation for primary great saphenous vein incompetence

Published: 14-03-2014
Last updated: 30-11-2024

To evaluate whether no utilization of compressive stockings is as effective as wearing a Class II Thrombo Embolic Deterrent (TED) stocking for 4 hours. Primary outcome is leg volume on post-operative day 14.The secondary objective is to study the...

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

Summary

ID

NL-OMON40253

Source
ToetsingOnline

Brief title
RCT comparing no compression therapy with 4 hours TED class II stocking

Condition

- Venous varices

Synonym
Varicose veins, venous insufficiency

Research involving

Human

Sponsors and support

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

Intervention

Keyword: compression therapy, radiofrequency ablation, Varicose veins

Outcome measures

Primary outcome

The primary endpoint is edema of the leg, objectified by volume measurements on post-operative day 14, performed by the investigator (TA Sigterman or HG Rensma). A Perometer® (Bösl Medizintechnik, Aachen- Deutschland) will be used. This leg volume measurement will be performed on three standardized points on the leg: 10 cm above the upper edge of the patella, at the tuberosity of the tibia and 5 cm below the tuberosity of the tibia.

Secondary outcome

Time to full recovery, post-operative pain and quality of life are secondary endpoints. The HRQOL will be estimated by the SF-36 questionnaire, which will be asked to fill in at randomization and after 2 weeks. At this point the patient will also be asked to determine the time in days to full recovery after the surgery. Post-operative pain will be scored by the patient on a standardized Visual Analogue Scale (VAS) from 1 to 10. Postoperative complications such as subcutaneous hematoma formation, thrombophlebitis and postoperative swelling will be documented.

Study description

Background summary

In developed countries lower extremity venous insufficiency affects up to 15% of men and 35% of women. Leading to significant reduction in health-related quality of life (HRQOL) and accounts for 1-2% of the total health care spending. There is a positive relationship between higher age and obesitas, and varicosis. Due to aging and increasing incidence and prevalence of obesity the incidence of varicosis is increasing. Radiofrequency ablation (RFA) is a widely accepted treatment for patients with primary great saphenous vein (GSV) incompetence. Currently, the usual aftercare consists of compression therapy for several hours up to several weeks. However, evidence to support this practice is based on limited case series describing small patient groups undergoing the old fashioned stripping technique. Today, this intervention is not current practice. The investigators suggest that compression after vein surgery reduces the risk of hematomas, edema and pain. However, recent studies conducted in the Atrium MC showed that there is no significant difference in the effectiveness of giving compression therapy for 4 hours versus 72 hours concerning pain, leg volume and recovery when RFA is performed. Furthermore, the overall complication rate was significantly less in the 4 hours group, compared to the 72 hours control group.

Study objective

To evaluate whether no utilization of compressive stockings is as effective as wearing a Class II Thrombo Embolic Deterrent (TED) stocking for 4 hours. Primary outcome is leg volume on post-operative day 14.

The secondary objective is to study the hinder and quality of life for the patients, post-operative pain and time to full recovery.

Study design

Prospective, single-blinded, randomized, controlled, single center, intervention study.

Intervention

After randomization, patients will be allocated to either no compressive therapy or a class II TED stocking for 4 hours.

Study burden and risks

All patients who are randomized to the study may benefit from a shorter

aftercare period or receive standard aftercare.

Possible benefits for the intervention group include:
• patient is less hindered in mobility by absence of a TED stocking to reach full mobility sooner
• less stress and postoperative care after radiofrequency ablation
• more comfort due to not wearing TED stocking

Risks to the intervention group
• possible higher chance for bleeding on the operated leg
• possible higher chance for edema to the operated leg
• possible higher chance for more pain on the operated leg, due to possibly more edema and hematoma

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 (RFA)

Exclusion criteria

- Ulcus cruris (C6 according to CEAP classification)
- Healed ulcus cruris (C5 according to CEAP classification)
- Non-compliance to therapy
- Bilateral radiofrequency ablation (RFA)

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):	23-01-2015
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2014

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	NL46948.096.13