Study comparing no compression therapy versus 4 hours of compression therapy after varicose vein surgery

Gepubliceerd: 12-05-2014 Laatst bijgewerkt: 13-12-2022

Compression therapy is not necessary after VNUS. Patients receiving no compression therapy after VNUS will have similar outcomes in post-operative pain, oedema, and HRQOL, post-operative complications, time to full recovery.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21362

Bron
Nationaal Trial Register

Verkorte titel
VNUS study

Aandoening

Varicose veins

Ondersteuning

Primaire sponsor: Atrium Medical center
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In developed countries lower extremity venous insufficiency affects up to 15% of men and 35% of women [1, 2]. Leading to significant reduction in health-related quality of life (HRQOL) and accounts for 1-2% of the total health care spending. 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. To the best of the authors knowledge no randomized controlled trial have been reported to this day comparing no compressive therapy versus any compressive therapy. 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. This study is under review in the European Journal of Vascular and Endovascular Surgery at this moment. (Results in addendum A)
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 at post-operative day 14. Secondary outcomes are pain and time to full recovery. Pain will be measured by using the standardized Visual Analalogue Scale (VAS) from 1 to 10.

The secondary objective is to study the hinder and quality of life for the patients, subsequently post-operative pain will be assessed.

Study design: Prospective, single-blinded, randomized, controlled, single center, intervention study.

Study population: 104 consecutive patients with primary GSV incompetence and treated by radiofrequency ablation presenting at the outpatient clinic.

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

Main study parameters/endpoints: The primary endpoint is edema of the leg, objectified by volume measurements at day 14 post-operative, 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.
Patients will also be asked to give permission to be approached one year after venous surgery has been performed to analyse reccurence rate of venous insufficiency. This will be performed utilizing Duplex-examination performed by vascular laborants of the clinical neurophysiological laboratorium (KNF) in the Atrium MC.

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. Time to full recovery 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. Furthermore, patients will be asked to keep a log book of their intake of any analgesic medication. See addendum B.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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

Doel van het onderzoek

Compression therapy is not necessary after VNUS. Patients receiving no compression therapy after VNUS will have similar outcomes in post-operative pain, oedema, and HRQOL, post-operative complications, time to full recovery.

Onderzoeksopzet

- Pre-operative

- 3 days post-operative

- 2 weeks post-operative

- 3 months post-operative

Onderzoeksproduct en/of interventie

No compression therapy

4 hours TED class 2 stockings

Contactpersonen

Publiek

Heelkunde, Atrium Medisch Centrum
Postbus 4446
T.A. Sigterman
Heerlen 6401 CX
The Netherlands
0031455766599 of 0031622424470, sein *7668

Wetenschappelijk

Heelkunde, Atrium Medisch Centrum
Postbus 4446
T.A. Sigterman
Heerlen 6401 CX
The Netherlands
0031455766599 of 0031622424470, sein *7668

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

- unilateral radiofrequency ablation (RFA)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ulcus cruris (C6 according to CEAP classification)

- healed ulcus cruris (C5 according to CEAP classification)

- non-compliance to therapy

- bilateral radiofrequency ablation (RFA)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4377
NTR-old	NTR4591
Ander register	: 13-T-159

Resultaten