

Effects of compressive bandages following stripping of greater saphenous vein (GSV) (EFFecten van COMpressief DRukverband na Varices OPeratie)

Submission date 14/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/08/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Varicose veins are swollen and enlarged veins that happen when the small valves inside them stop working properly. This means that the blood is able to flow backwards and collect in the vein. In developed countries, up to 15% of men and 35% of women develop varicose veins. People at most risk of the condition are pregnant women, people that are obese (very overweight) and the elderly. Removing the affected vein, in a process called stripping, is one of the treatments available for treating varicose veins. Currently, the usual aftercare after stripping of a varicose vein is compression therapy, where compression stockings are worn for between a few hours and several weeks. However, evidence to support this practice is based on a few test cases describing small patient groups undergoing stripping. This study involves comparing the effects of 4 hours of compressive therapy compared to a more usual 72 hours following the stripping of the greater saphenous vein (the largest vein in the leg)

Who can participate?

Adult varicose vein sufferers who have undergone stripping of one or both greater saphenous veins.

What does the study involve?

Participants will be randomly allocated to one of two groups. Those in group 1 (intervention group) wear compressive bandages for 4 hours after surgery. Those in group 2 (control group) wear compressive bandages for 72 hours after surgery. All patients were seen 3 days and then 14 days after surgery to check on progress.

What are the possible benefits and risks of participating?

Possible benefits for the intervention group may include becoming more mobile more quickly due to the shorter duration of compressive therapy. Possible risks may be more postoperative (after surgery) oedema (water accumulating in the leg) and higher risk of bleeding.

Where is the study run from?
Atrium Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
February 2010 to June 2011

Who is funding the study?
Atrium Medical Centre (Netherlands)

Who is the main contact?
Dr TA Sigterman
timsigterman@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr TA Sigterman

Contact details
Hoograamstraat 113
maastricht
Netherlands
6211BJ

Additional identifiers

Protocol serial number
09-T-76

Study information

Scientific Title
Effects of compressive bandages following stripping of GSV

Acronym
EFFCOM DRUVOP

Study objectives
Wearing of compressive stockings during a period of 4 hours after stripping of greater saphena vein (GSV) is as effective as wearing compressive stockings for 72 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical ethical committee of the Atrium-orbis Zuyd, Heerlen The Netherlands; 14/02/2010

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Venous insufficiency

Interventions

Randomization of subjects with the aid of a computer performed randomisation list generated. Randomization works with a block size of 8 subjects to promote equal distribution of numbers of patients on the two treatment groups. All patients gave written consent to participate in the study.

Study population:

The study population will consist of two groups:

1. The group of 50 patients who receive postoperative compressive bandages for 4 hours (intervention group).
2. A group of 50 patients who receive postoperative compressive bandages for 72 hours (control group).

Follow-up:

Patients were seen day 3 and day 14 postoperative for primary and secondary outcomes.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The primary endpoint is edema of the leg, objectified by volume measurements at day 14 post-operative, performed by the investigator. 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

Key secondary outcome(s)

1. Post-operative pain will be scored by the patient on a standardized Visual Analogue Scale (VAS) from 1 to 10.
2. Postoperative complications such as subcutaneous hematoma formation, thrombophlebitis and postoperative swelling will be documented.
3. 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.

Completion date

18/06/2011

Eligibility

Key inclusion criteria

1. Primary insufficiency of GSV (CEAP classification; C2 en C3)
2. Unilateral crossectomy and strip of GSV
3. Bilateral crossectomy and strip of GSV

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. CEAP classification C5-C6
2. Non-compliance with postoperative compressive therapy

Date of first enrolment

24/02/2010

Date of final enrolment

18/06/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

Hoogaamstraat 113

maastricht

Netherlands

6211BJ

Sponsor information

Organisation

Atrium Medical Centre (Atrium Medisch Centrum) (Netherlands)

ROR

<https://ror.org/0367sye10>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration