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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

Registration date
20/08/2014

Overall study status
Completed

Last Edited
20/08/2014

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures
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.

Overall study start date
24/02/2010

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

Age group
Adult

Sex
Both

Target number of participants
100

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
Hoograamstraat 113
maastricht
Netherlands
6211BJ

Sponsor information

Organisation
Atrium Medical Centre (Atrium Medisch Centrum) (Netherlands)

Sponsor details
c/o TA Sigterman
Henri Dunantstraat 5
Heerlen
Netherlands
6419PC

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0367sye10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration