Comparison of costs and patient reported outcomes of endovenous techniques in the treatment of incompetent saphenous veins: A single center, double blinded, randomized controlled trial

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We want to investigate the patient satisfaction after both treatments and differentiation in direct costs between the radiofrequency ablation (by VNUS closureFAST) and treatment with the radial fiber 1470 nm endolaser. We want to compare both...

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

Summary

ID

NL-OMON34867

Source
ToetsingOnline

Brief title
endovenous techniques in truncal varicose veins

Condition

- Venous varices

Synonym
saphenous incompetence, varicose veins

Research involving
Human

Sponsors and support

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

Intervention

Keyword: costs, endovenous techniques, patient reported outcomes, saphenous veins, truncal veins

Outcome measures

Primary outcome

The primary outcome measure is the patient treatment satisfaction in terms of health related quality of life improvement, (post-operative) pain scores, clinical changes (venous clinical severity scores and CEAP-classification) and (serious) side effects.

Quality of life changes will be measured using the EuroQol-5D questionnaire (at baseline, 1 , 2 , 3 week(s) after treatment and one month after treatment).

Improvement of clinical symptoms will be measured by the Aberdeen Varicose Vein Questionnaire (AVVQ) (at baseline , 2 weeks- and one month after treatment).

Before treatment and one month after treatment venous clinical severity scores and CEAP-classification will be performed by an independant blinded clinician.

Aberdeen Varicose Veins Questionnaire (AVVQ) and Venous Clinical Severity Score (VCSS) surveys are used to appraise the quality of life and symptomatic alleviation.

Post-operative pain sensation will be scaled by VAS-scores and the 'pain questionnaire' at 48 hours-, 1 , 2, 3 week (s), and 1 month after treatment.

Patient preferences will be measured by conjoint analysis.

Patients will have follow up visits after one week and one month. At week 1, 2,

3 and 4 they will fill in the questionnaires at home.

Side effects are monitored during follow up visits.

Secondary outcome

Secondary outcome measures are direct costs of both treatments. Direct costs are defined as costs on hospital level and will be determined by using cost-prices of the hospital financial department and linking these to the medical activities. When cost-prices are not available, additional cost-price calculations will be performed. Failing of procedures, in case, for example, the catheter can not be advanced into the vein, is taken into account and will be summarized. A bootstrap analysis will be performed to analyse cost-differences between the two treatment arms.

Study description

Background summary

Venous insuffiency of the lower limbs is a common medical condition and accounts for substantial expenditure in the western world. Results from several epidemiologic studies show that a quarter of the adult population has insufficency of the truncal veins in the legs. Valvular incompetence of the great and small saphenous vein is the most frequent cause of venous insufficiency. Since the incidence increases with age in a linear manner, the prevalence will increase in the coming years.
The treatment of superficial venous disease has undergone enormous changes during the past decade. The introduction of minimal invasive endovenous techniques has proven to be an effective intervention. These techniques include echo-guided foam sclerotherapy, endovenous radiofrequency ablation (RFA; VNUS closureFAST) and laser (EVLA), and were introduced to improve efficiency, optimalize patient health related quality of life, enlarge patients treatment satisfaction and reduce serious side effects, costs and postoperative pain.
The endovenous lasertherapy (EVLA) damages the vein wall with a high temperature produced by laser energy. Radiofrequency ablation (RFA) is also a thermal ablation technique, based on radiofrequency energy.

Compared to the *gold standard*, the surgical ligation and stripping procedure, the recovery time of patients after endovenous treatment is faster and there is less postoperative pain. Studies comparing EVLT and RFA with surgical stripping suggested that they were equally effective (comparable recurrence rates), but patient reported outcomes were in favour of the minimal invasive endovenous techniques.
In this study we will compare the thermal endovenous techniques , endolaser (EVLT) versus radiofrequency ablation (RFA). Both techniques have proven to be safe and are comparable effective.
Our primary objective is the hypothesis that both techniques have the same patient satisfaction, counted in terms of quality of life improvement, post operative pain, side effects and clinical changes. We want to refute the supposition that the VNUS closureFAST technique accounts for higher patient satisfaction as concluded from the RECOVERY study in which RFA (VENUSclosureFAST) is compared with the 980 nm endolaser. Recent research has shown that the new radial fiber 1470 nm endolaser, compared to historical endolaser control (980 nm, 80 J/cm, 12 W) minimizes post-operative pain and ecchymosis. This implies that vein-wall perforations (causing these side effects) are minimized with this system. This can be explained by the fact that this water specific laser wavelength (WSLW) is preferentially absorbed by water 40 times more than a 980-nm wavelength. It is hypothesized that water specific laser wavelengths would more readily target the vein wall and more readily ablate veins at lower energy densities, resulting in fewer side effects. 2 comparative studies have demonstrated that patients treated with WSLW reported less post-operative pain, used less painkillers, and were less likely to have ecchymosis.

Study objective

We want to investigate the patient satisfaction after both treatments and differentiation in direct costs between the radiofrequency ablation (by VNUS closureFAST) and treatment with the radial fiber 1470 nm endolaser.
We want to compare both treatments in patients with incompetent saphenous veins (great saphenous vein (GSV) and the small saphenous vein (SSV), There is no prospective randomized trial known comparing the VNUS closureFAST (RFA) with the radial fiber 1470 nm endolaser (EVLT). Noticing both techniques are comparable effective, lower costs together with greater patient satisfaction will lead to firm recommendations. A comparison of costs and patient reported outcomes is needed to enable us to make these firm recommendations. In our prospective trial patient reported outcome is defined as patient satisfaction, in terms of quality of life improvement, postoperative pain, side events and clinical changes. Eventually we want to investigate if there is a correlation between the difference in costs and patient satisfaction.

Study design

The study will be a single-center, double blinded, randomized controlled trial wherein patients with a primary incompetent truncal saphenous vein are randomly assigned either to 1) laser (EVLT) or 2) radiofrequent ablation (RF). To maintain the double blinded nature of the study, the actual treatment procedure is not discussed with the participants. The study population will consist of patients with an incompetent truncal saphenous vein (GSV or SSV) and will be recruited from visits to our outpatient*s clinic of the department of Dermatology of the University Hospital Maastricht (MUMC+). There will be a follow up of 4 weeks after treatment. We believe that most postprocedural effects resolve after one month. Follow up visits will be planned at week 1 week and 1 month. When we see exceptional abnormalities at 1 month we will enlarge the follow up for those patients till 6 weeks (regular control visit for patients treated with VNUSclosureFAST or endolaser). The independent (blinded) clinician, who is present at baseline and at each follow up visit, evaluates the post-procedural effects (occlusion, venous clinical severity score, CEAP, side effects) and does not know in which therapy-arm the patient is treated. This is possible because of the same post-procedural marks. Questionnaires will be filled in at baseline and 1, 2, 3 and 4 weeks after treatment.
Clinical severity and CEAP-scores will be scaled at baseline and 4 weeks after treatment by the same independent blinded clinician, not knowing in which treatment arm the patient is treated.
Control Duplex will take place 1 week and 4 weeks after treatment (occlusion, flow, reflux) and will be performed by the same independant blinded clinician.
VAS-painscores and the 'pain questionnaire' will be collected 48 hours after treatment and after 1, 2, 3 and 4 weeks.
See flow chart (protocol page 9)

Intervention

Treatment of saphenous incompetence with either 1. VNUSclosureFAST-method or 2. radial fiber 1470 nm endolaser

Study burden and risks

Risks of the research are the normal risks which can possible occur from the treatment with radiofrequent ablation or endolaser therapy.
Ecchymosis, pain, induration, skin burns, dysesthesia, superficial thrombophlebitis, and hematoma are classified as minor complications. Deep vein thrombosis and nerve injury are classified as major complications.
After one week there is a regular follow up visit and ultrasound control of the junction is performed to exclude thrombosis. In case of complains patients can be seen earlier in our outpatient clinic and a ultrasound will be made.
After the radiofrequent ablation or endolaser technique patients can feel some pain for some days, a recipe for painkillers is prescribed.
There is an independent specialist for the patients where they can go with

questions and complaints about the research.

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

primary saphenous incompetence
normal deep venous system
Reflux time >0.5 s after distal compression in standing position (in GSV or SSV)
Patient should be physical able and willing to be treated with one of the two treatments
Age: >18 years
No sex discrimination
No restriction in ethnic background, only if communication problems can occur due to language problems

diameter >4mm (due to the cathether used in both techniques)

Exclusion criteria

Signs of DVT-residues visible on duplex
Thrombus in vein of interest
Previous GSV or SSV treatment
Pregnancy
Known malignancy
Known adverse reaction for used local anaesthesia

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22362
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCTnummervolgt,aanvraagisingendiend
CCMO	NL30280.068.09
OMON	NL-OMON22362