Comparative randomized clinical trial of Steam Ablation versus Endovenous Laser Ablation for the treatment of Great Saphenous Veins

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To test whether the anatomical success rate of Steam Ablation is not inferior to that of EVLA in treatment of GSV insufficiency and compare the treatment related complications, patient reported outcomes and cost-effectiveness analyses between EVLA...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON32935

Source
ToetsingOnline

Brief title
LAST Trial

Condition

- Skin vascular abnormalities
- Vascular therapeutic procedures
- Venous varices

Synonym
GSV insufficiency, varicose veins

Research involving
Human

Sponsors and support

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

Intervention

Keyword: endovenous, GSV, laser, steam

Outcome measures

Primary outcome

1. Obliteration of varicose vein and absence of reflux (>0.5 sec. of retrograde flow) along the treated segment of the GSV. This is measured using US examination. The rates will be compared between EVLA and SVS at time 12 and 52 weeks.

2. Varicose Vein Severity score (VVSS), (assessed with a questionnaire).

Secondary outcome

1. Treatment complications:

a. Major complications: deep and superficial venous thrombosis (embolic events), nerve injury, skin burns, and (sub)cutaneous infections.

b. Minor complications: ecchymosis, pain and hyperpigmentation.

The rates will be compared between EVLA and Steam Ablation at time 2 and 12 weeks.

2. Patient reported outcomes:

a. Health related quality of life will be measured using the Dutch Aberdeen Questionnaire.

b. Treatment satisfaction will be assessed.

c. Pain score.

3. Cost-effectiveness analysis (CEA):

a. Direct and indirect costs associated with EVLA and Steam Ablation will be

estimated.

b. Quality adjusted life years will be assessed using the EQ-5D.

Study description

Background summary

The treatment of varicose veins reduces the symptoms and complications of chronic venous insufficiency and improves HRQOL of patients. Surgery has been the standard of care in the treatment of saphenous varicose veins. The great saphenous vein (GSV) is traditionally treated by high ligation at the saphenofemoral junction (SFJ) followed by a short stripping to the knee. Most commonly, the small saphenous vein (SSV) is ligated at the saphenopopliteal junction (SPJ) only. Recurrence rates after surgery are about 25% and 50% at 5 years for the GSV and SSV, respectively. A study with a mean follow-up of 34 years showed recurrence in 60% of 125 limbs after SFJ ligation and GSV stripping. Failure after surgery may be due to neovascularization, double saphenous vein system, technical and tactical failure (up to 30%), and/or incomplete procedure. Other disadvantages of surgical therapy are the use of general or epidural anesthesia, presence of at least two fairly long scars, postoperative down-time, and risk of adverse events such as femoral artery and/or vein damage, wound infection, neurologic injury (about 7% in short to 40% in long stripping of GSV) and lymphatic complications. To improve efficacy, patients* HRQOL, and treatment satisfaction and to reduce serious side effects, costs, and postoperative pain, new minimally invasive techniques, such as ultrasound-guided foam sclerotherapy (UGFS), endovenous laser ablation (EVLA), and radiofrequency ablation (RFA), have been introduced in the last decade. The mechanism of ablation of the latter two therapies is based on heating (of at least 85 degrees Celsius) of the venous structure including the creation of intravascular *steam bubbles* either using laser emission or radiofrequency. From this mechanistic perspective, a new minimally invasive endovenous therapy has been developed that generates and administers high pressure steam in the varicose vein (i.e., Steam Vein Sclerosis [SVS]). The advantages of this new procedure are mechanistic, costs and possibly patient satifaction. The steam generator is less expensive than existing laser and

radiofrequency devices and requires little to no maintenance. In contrast to EVLA, RFA and UGFS, Steam Ablation uses sterile water which is natural body*s substance and has not the possible disadvantage of inducing harm using or generating exogenous substances. Because the induced temperature rise is limited (in accordance with RFA), it is likely that the treatment related symptoms (i.e., pain and bruising) and complication rate is lower than EVLA, which may increase patient*s comfort and treatment safety.

Study objective

To test whether the anatomical success rate of Steam Ablation is not inferior to that of EVLA in treatment of GSV insufficiency and compare the treatment related complications, patient reported outcomes and cost-effectiveness analyses between EVLA and Steam Ablation.

Study design

A non-inferiority randomized clinical trial with one year follow up.

Intervention

Endovenous Laser Ablation or Steam Ablation. Both procedures are endovenous techniques based on heating the varicose vein from inside reulting in closure of the treated vein.

Study burden and risks

The treatments within the trial setting are either identical or almost the same as the treatment that would be offered to the regular patient. The aim of the trial is to compare effectivity, complication rate, safety, patient-satisfaction and cost-effectiveness. The patient participating in the Trial should attend the Department of Dermatology once more than the regular patient, which will take approximately 15 minutes. Furthermore patients are asked to fill in two questionnaires, which will take approximately 30 minutes.

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 insufficiency of GSV
patients over 18 years old
symptoms of chronic venous insufficiency
informed consent

Exclusion criteria

agenesis of deep venous system
acute deep or superficial vein thrombosis
vascular malformation or syndrome
post-thrombotic syndrome of occlusive type

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL28217.078.09