Endovenous laser ablation versus mechano-chemical endovenous ablation in the treatment of great saphenous incompetence: a multicentric, randomized controlled trial

Published: 16-08-2011
Last updated: 27-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36499

Source
ToetsingOnline

Brief title
Clari-Laser study

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym
varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Patienten worden behandeld in een bestaand DBC traject;geldend voor varices van de onderste extremiteiten

Intervention

Keyword: Endovenous, Mechano-chemical endovenous ablation, Treatment, Varicose veins

Outcome measures

Primary outcome

Primary study parameters:

- Technical success (occlussion percentage, demonstrated by duplex)

- Clinical success (CEAP, VCSS)

- Peroperative pain (VAS score)

- Postoperative pain for 2 weeks (VAS score, amount of analgesia used)

Secondary outcome

Secondary study parameters:

- Postoperative complications

- Disease specific quality of life (AVVQ, SF-36)

- Time from treatment to resumption of normal activities

- Procedural lenght

- Costs

Study description

Background summary

Varicose veins are a common problem in the Western world. Epidemiological studies show that 25% of adults have some form of varicose veins. Women are two

to three times more affected than men. The incidence of varicose veins increases steadily with age and are among the top ten of the complaints that people visit their GP. The main risk factors include prolonged standing or sitting, pregnancy, sex and age. Symptoms of varicose veins are variable and range from cosmetic complaints to venous ulcers.
Stripping the great saphenous vein (GSV) has been the gold standard for GSV incompetence for more than 100 years. Surgery is performed under regional or general anesthesia and has a high recurrence rate of 18-40% in 5 years. In addition, surgery can leads to significant postoperative symptoms, particularly pain and hematoma formation and the risk of injury to the saphenous nerve.
Recently, endovenous techniques has been developed for the treatment of varicose veins. Endovenous laser ablation (EVLA) is an accepted technique nowadays and is frequently used in practice. This technique, which uses heat as treatment source, can be performed with local anesthesia. In addition, EVLA causes less hematoma formation, pain, and superior cosmetics and earlier resumption of normal activities and work compared to traditional surgical stripping.
Thermal ablative modalities are at higher risk to damage the surrounding tissues of the vein. For this reason, patients are treated with tumiscence anesthesia, which requires multiple punctures around the vein. With tumescence anesthesia a liquid column is injected around the vessel, which is a painfull experience by most patients. Despite tumiscence anesthesia still a subset of patients have postoperative pain, which can last up to weeks.

A new innovative technique, mechano-chemical endovenous ablation (MECEA), using the ClariVeinTM system was recently developed. This technique uses a rotating wire in a catheter to create mechanical damage to the endothelium of the vessel. At the same time a sclerosans is injected at the end of the catheter, occluding the vein. With MECEA no heating of the vein is used. Tumiscence anesthesia is redundant and complications that occur in thermal ablative modalities, such as pain, hematoma formation, induration and paresthesias could be reduced.
In Europe, the ClariVein device is registrered on April 26, 2010, CE 558 723.
Results of the first human study in USA showed that occlussion percentage after 6 months was 97%. In this study, 30 patients with primary GSV insufficiency were treated without tumescence anesthesia or sedation. The average age was 55 years. The diameter of the GSV near the saphenofemoral junction was 8.1 mm on average . The treated section of the saphenous vein magna averaged 36 cm. After a follow-up of 6 monthsm, 29 of the 30 treated GSV were occluded . Echymosis were seen in 3 patients. In addition, there was no deep vein thrombosis or related complications to sclerosans.
We have recently reported a second study on the safety and efficacy of MECEA in 30 patients. The success rate after 6 weeks was 97%. With duplex examination recanalization was observed in 1 patient. This patient underwent a successful recurrent treatment with MECEA. Three patients had an open segment of the proximal GSV. Therefore, the treatment protocol was adapted, positioning the tip of the rotating wire closer to the saphenofemoral junction. The mean

treatment time was 20 minutes and patients had median pain scores of 4 during treatment (visual analog scale 0-10). The 'Venous Clinical Severity Score ", an objective measure of varices-specific symptoms improved after treatment. Patients were very satisfacted after treatment with an average of 8.8 (0-10 scale). Near the injection site, small ecchymosis were observed in 9 patients.

Study objective

The Clari-laser study is designed to evaluate the following questions:

1. What is the succes rate of MECEA versus EVLA on short and long term?
2. Are the results after treatment both clinically and technically comparable?
3. What are the per-and post-procedural complications of MECEA versus EVLA?
4. What are the pain scores of patients during treatment and 2 weeks after treatment of MECEA versus EVLA?
5. Are there differences between intervention duration of MECEA versus EVLA?
6. What are the costs of treatment of MECEA versus EVLA?
7.Does quality of life improve after treatment, MECEA versus EVLA?

Study design

814 patients with primary great saphenous incompetence magna are included in the Clari-laser study after signing informed consent . The preprocedural status will be determined by the CEAP score and VCSS (Venous Clinical Severity Score). After randomization, the GSV is obliterated in day treatment:
- Group / arm 1: endovenous laser ablation (EVLA)
- Group / arm 2: mechano-chemical endovenous ablation (MECEA)

After 4 weeks, 6 months, 1 year, 2 years and 5 years patients are seen on the outpatient clinic to observe the clinical success after treatment objectively. During this visit, a duplex examination is also performed to assess if the GSV remains obliterated. Duplex examination is done according to a standardized protocol.
Also, pain scores after treatment are evaluated using a linear VAS score of 0-10. To assess secondary endpoints, SF-36 healthy nature test and the recently validated "Dutch translated Aberdeen varicose Vein Questionnaire are used. Both questionnaires are completed preoperatively, after 4 weeks, 6 months, 1 year, 2 years and 5 years of follow-up. After 4 weeks, any small branch varicosities can be treated.

Intervention

Endovenous laser ablation

Endovenous laser therapy or ablation is a minimally invasive treatment for

varicose vein incompetence. This technique uses laser light to heat the greater saphenous vein. The endovenous catheter is inserted into the vein and laser energy is delivered to the endothelium with collapsing and sealing of the vein as effect. During the Clari-laser study, all participating centers are using the same laser equipment.
The procedure starts with ultrasound guided puncture of the vein with a needle. Through the needle a guidewire inserted into the vein. After the guidewire is in place, the needle is removed, and a small cutaneous incision of 3 mm is made. An introducer sheath will pass over the guidewire and is positioned a few centimeters below the saphenofemoral junction. Subsequently, the laser fiber can be introduced after removing the guidewire.
The exact positioning of the laserfiber is the most pivotal step in endovenous laser ablation, and is performed under ultrasound guidance, 1.5 to 2 cm distal to the saphenofemoral junction. Then, tumiscence anesthesia is administrered around the great saphenous vein. The fiber laser is activated and withdrawn at an average speed of 2mm/sec, depending on the diameter of the VSM, until the entire vein is treated with 60-70 J / cm. After treatment, the deep venous system is controlled by ultrasound. Eventually, the treated vein develops into to scar tissue.
During the procedure, special safety glasses are worn by patient and staff. A supportive compression stocking (Class 2, 30-40 mmHg) will be applied for 24 hours continuously and for 2 weeks daily. Patients can resume to normal activities directly after the procedure

Mechano-Endovenous Chemical Ablation (MECEA)

MECEA is a new technique for endovenous treatment of great saphenous imcompetence using the ClariVein devive. ClariVein device is an infusion catheter which is designed to administer a sclerosant in the incompetent vein through an opening at the end of the catheter. A iron wire extends through the whole catheter, with a small iron ball at the end. The catheter, together with iron wire are connected to a motorized handle that allows rotation of the metal wire.
The incompetent vein is punctured with a 17-gauge needle, usually at the knee. A 4 Fr or 5Fr introduction sheath is introduced into the vein, over a short guidewire. Then, the Clarivein catheter is introduced and placed 0.5 cm below the saphenofemoral junction without using a guidewire. Importantly, the position of the catheter is controlled by ultrasound, as with other endovenous techniques, to minimize the risk of deep venous thrombosis after treatment. The iron ball at the end of the wire improves ultrasound-guided detection and is easy to visualize. The patient is placed in a neutral horizontal position, when wire is activated with a motorized handle. The purpose of the rotating wirer is fourfold: (1) promoting the coagulation activation by minimal mechanical damage to the endothelium, (2) inducing a vasospasm which reduces the diameter of the vein, (3) increasing the action of sclerosans by an increase in surface, (4) ensuring an even distribution of the sclerosans at the endothelium.

For 5 seconds, the rotating wire is activated to induce vasospasm. Then the rotating wire is slowly withdrawn with a speed of about 7 seconds per centimeter, while the sclerosans is continuously injected. After the ClariVein system is removed, the patient receives a compression stocking with a pressure of 20-30 mmHg for two weeks, on daily basis. Patients are asked to walk immediately after treatment and advised to to resume daily activities as soon as possible.
Polidocanol (Aethoxysklerol) is used as sclerosans, which is the only registered sclerosans in the Netherlands and is often used for sclerotherapy of reticular veins. The maximum amount Aethoxysklerol depends on the weight of the patient and will always be less than 2 mg / kg. The first proximal segment of the VSM (10 cm) is treated with Aethoxysklerol 2%, when the remainder part of the greater saphenous vein is treated with Aethoxysklerol 1.5%.
Prior to treatment, the maximum allowable amount Aethoxysklerol is determined for each patient. Then the length of the treated vein is measured. Both values are listed on the study form. After treatment, the deep venous system controlled by ultrasound.

Study burden and risks

Patients with primary great saphenous incompetence are treated in an outpatient setting. The puncture site of the catheter is not different from other endovenous techniques.
In addition, patient have 5 duplex examinations in the postoperative period (4 weeks, 6 months, 1 year, 2 years, 5 years), which is four times higher than with regular treatment. After all duplex examinations patients, 2 quality of live questionairs are completed.

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

1. Primary great saphenous incompetence
2. C2-C4 varicose veins
3. Ultrasound criteria have to be sufficient for endovenous therapy: diameter of the great saphenous vein > 3mm and < 12mm, not tortuous
4. Signed informed consent
5. Patient willing for follow-up
6. Age > 18 years and < 80 years

Exclusion criteria

1. Patient not capable for informed consent
2. Pregnancy and lactation
3. Surgical or endovenous therapy for ipsilateral varicose vein incompetence in history
4. Deep venous trombosis in treated leg
5. Use of oral anticoagulantia
6. Contraindications or allergy for sclerosant
7. Immobilisation
8. Coagulation disorders or increased risk of tromboembolic complications
9. Peripheral arterial disease, Fontaine 3-4
10. Severe renal failure
11. Liver insufficiency
12. Other treatment modality is more appropriate for varicose vein treatment

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2012
Enrollment:	814
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-12-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL35276.091.11

Study results

Date completed: 10-02-2021

Actual enrolment: 224

Summary results
Trial ended prematurely