Mechanochemical Endovenous ablation (MOCATM) versus radiofrequency ablation (RFA) in the treatment of primary Small Saphenous vein Insufficiency: a multicentre randomized trial

Published: 13-01-2014
Last updated: 15-05-2024

Objective: To evaluate the anatomical success of MOCA versus RFA in treatment of symptomatic insufficient SSV.

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

Summary

ID

NL-OMON40762

Source
ToetsingOnline

Brief title
MESSI-trial

Condition

- Venous varices

Synonym
varicose veins, venous insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,deelnemende secties vaatchirurgie en stichting VARYSTA (onderzoeksfonds Rijnstate / Nieuwegein)

Intervention

Keyword: clarivein, polidocanol, small saphenous vein (SSV), varicose veins

Outcome measures

Primary outcome

The primary endpoint is anatomical success at 1 year follow-up.

Secondary outcome

Secondary study parameters

- Pain during and after procedure

- Initial technical success

- Clinical success (CEAP, VCSS, QoL)

- Complications

- Length of procedure

Study description

Background summary

Varicose veins are a common problem in the Western world. Epidemiological studies show that 25% of adults have some characteristics 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 age1. Symptoms of varicose veins are variable and range from cosmetic complaints to venous ulcers2.These problems are mostly associated with insufficiency of great saphenous veins (GSVs); however, insufficiency of the small saphenous vein (SSV) is responsible in 15% of patients with varicose veins.3

Until the 1990s, high ligation, with or without surgical stripping, was the preferred option for venous insufficiency, although there was no standard in surgical treatment of SSV insufficiency.4Recurrence of varicose veins after conventional surgery is common.5,6 Recurrence rates of 25-50% are found following surgery after a follow-up period of three to five years7-9In addition, surgery can leads to significant postoperative symptoms, particularly pain and hematoma formation. In surgical treatment of SSV insufficiency injury to sural and peroneal nerve is a major concern.
The introduction of minimally invasive endothermal catheter modalities, including endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), has revolutionized the treatment of varicose veins. These have become the preferred techniques, with higher success rates7-9. The success rates of endovenous ablation by RFA are frequently studied in GSV. Occlusion rates in SSV are thought to be approximately similar to those in GSV. Van de Bos et al showed in their meta-analysis occlusion in 88% of treated veins at 1 year follow up. Thermal ablative techniques, which use heat as treatment source, can be performed with local anesthesia. In SSV sural nerve injuries after thermal ablation are described in up to 11%10. For this reason, patients are treated with tumescence anaesthesia, which requires multiple punctures around the vein. With tumescence anesthesia a liquid column is injected around the vessel, which is a painful experience by most patients. Despite tumescence anesthesia postoperative pain is inherent to thermal therapies and can last up to weeks.RFA causes less hematoma formation, pain, and superior cosmetics and earlier resumption of normal activities and work compared to traditional surgical stripping11-12.

A new innovative technique, mechanochemical endovenous ablation (MOCATM), using the ClariVein® system is recently developed. This technique uses a rotating wire in a catheter to create mechanical damage to the endothelium of the vessel. Simultanously a sclerosans is injected at the end of the catheter, occluding the vein. With MOCATM no heating of the vein is used. Tumescence 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 registered on April 26, 2010, CE 558723.

Two studies describing the safety and the initial results of MOCA* were recently published. Elias et al.13 showed an occlusion rate in GSV of 96.7% after MOCA*using sodium tetradecyl sulfate (Sotradecol®). The average follow-up in these patients was 260 days. MOCA* combining Clarivein® with polidocanol showed occlusion in 97% of treated GSV at 6 weeks after treatment, and partial recanalisation was described in 10%. No major complications occurred, and minor complains were acceptable in amount and severity13,14.Our study group recently described the first results of MOCA* in SSV. MOCA* of SSV is a feasible and safe treatment. Occlusion rates are 100% at 6 weeks follow up and 97% at 1 year. In SSV no major complications were seen, especially no nerve injury. Minor complications were similar to those in GSV. Pain scores were low (2; IQR

2-4). The 'Venous Clinical Severity Score ", an objective measure of varicose vein-specific symptoms improved significantly from 3.0 (interquartile range [IQR] 2-5) before treatment to 1.0 (IQR 1-3, P< 0.001) at 6 weeks and to 1.0 (IQR 1-2, P< 0.001) at 1 year after treatment. Patients were satisfied after treatment with an average of 8.8 (0-10 point scale)15.

Study objective

Objective: To evaluate the anatomical success of MOCA versus RFA in treatment of symptomatic insufficient SSV.

Study design

The MESSI study is a randomized controlled, multicentre trial, initiated by the St. Antonius Hospital. The following Dutch hospitals will participate in the study:
- Rijnstate Hospital, Arnhem
- Rode Kruis Ziekenhuis Beverwijk
- St. Antonius Hospital, Nieuwegein
Other centers may be invited to participate in the study.

Intervention

"Experimental"
- Mechano-chemical ablation of insufficient SSV

"Control"
-Radiofrequency ablation of insufficient SSV

Study burden and risks

Both experimental and control intervention are accepted therapies in treatment of insufficient SSVs.

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 SSV incompetence
2. Symptomatic varicose veins, C1-C5
3. Duplex ultrasound criteria meet criteria for general endovenous treatment: diameter of small saphenous vein > 3 mm and < 12 mm, non-tortuous
4. Signed informed consent
5. Patient is willing to participate in follow up
6. Age> 18 year and < 80 year

Exclusion criteria

1. Patient is incapable of informed consent
2. Pregnancy and lactation
3. C6 varicose veins
4. Pervious surgical or endovenous treatment of the affected vein
5. History of deep venous thrombosis in the affected leg
6. Oral anticoagulants
7. Contraindication or known allergy to sclerosans
8. Immobilization
9. Coagulation disorders or increased risk of thrombo-embolic complications: known coagulation disorders as hemophilia A, hemophilia B, Von Willebrandt disease, Glanzmann disease, factor VII-deficiency, idiopathic trombocytopenic purpura, factor V Leiden, deep venous thrombosis or pulmonary embolism in medical history
10. Fontaine III of IV peripheral arterial disease

11. Severe renal insufficiency: known glomerular filtration rate < 30 mL/min
12. Liver disease, associated with changes in coagulation, anemnestic evidence of bleeding as epistaxis and spontaneous hematoma, liver cirrhosis.

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:	Recruitment stopped
Start date (anticipated):	13-01-2014
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	ClariVein
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-08-2014

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 26692
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42781.100.13
OMON	NL-OMON26692