Registry of the treatment of primary insufficiency of the great saphenous vein with a diameter >/= 12 mm, antero-lateral branches, or great saphenous vein insufficiency below the knee with mechano-chemical endovenous ablation (MOCA)

Published: 20-10-2014
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The goal of this registry study is to provide insight in the safety and efficacy of treatment with MOCA for primary insufficiency of the GSV with a diameter >/=12mm, insufficient antero-lateral branches (

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

Summary

ID

NL-OMON41034

Source
ToetsingOnline

Brief title
MOCA-XL

Condition

- Venous varices

Synonym
dilated veins, Varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: De deelnemende ziekenhuizen financieren de inzet van onderzoekspersoneel uit eigen onderzoeksfondsen.

Intervention

Keyword: below-knee and branches, endovenous, mechano-chemical ablation, treatment large varicose veins

Outcome measures

Primary outcome

- Anatomical success (occlusion rate, based on ultrasound)

- Clinical success (CEAP, VCSS)

- Postoperative complications, especially sensibility disturbances

Secondary outcome

- Per-operative pain (VAS-score)

- Post-operative pain during first 2 weeks (VAS-score, used pain medication)

- Disease specific and general health questionnaire (AVVQ, SF-36)

- Time to resume daily activities and work

- Intervention duration

Study description

Background summary

Varicose veins are a common problem in the World. From epidemiological studies we know that a quarter of the adult population suffers from some sort of varicose veins. Women suffer two to three times more often from varicose veins than men. The occurrence of varicose veins increase with increasing age and is

one of the top ten complaints for which patients visit their general practitioner. De main risk factors for developing varicose veins are enduring standing or sitting, pregnancy, female gender and age. Symptoms are divers and vary from cosmetic complaints to difficult to treat venous ulcers.
Last few years endovenous techniques have been developed for the primary treatment of insufficient varicose veins. Radiofrequent ablation (RFA)is, besides endovenous laser ablation (EVLA), an accepted technique and is frequently applied in clinical practice. This technique, that uses heat, has the important advantage that the treatment can be performed using a slight local anaesthesia. Besides that, RFA causes less hematoma, pain, a superior cosmetic and patient are able to restart daily activities sooner than compared to the classical surgical treatment. Because RFA using heat technology, damage can occur in the surrounding tissues. That is the reason for using tumiscentie anaesthesia, for which multiple injections are needed. A column of liquid is placed surrounding the vein. Many patients experience this column as inconvenient and despite this form of anaesthesia part of the treated patient population experiences pain after the treatment that can last up to weeks.
A newer endovenous technique is mechano-chemical ablation (MOCA) has been developed, using the ClariVein system. This technique uses intentional mechanical damage to the endothelium of the vene by means of a rotating catheter. At the same time a sclerosans is injected, and as a result the vene occludes. So this technique does not use heat technology. Tumescent anaesthesia is therefore not needed and complications related to techniques using heat (RFA and EVLA) such as burning, pain, hematoma, indurations, and paresthesia could be reduced or even be prevented.
MOCA proved to be a safe and effective alternative treatment for both insufficient great saphenous veins (GSV) and small saphenous veins (SSV). Especially for the treatment of the below-knee GSV and the treatment of superficial branches (such as the antero-lateral branches), there is a risk for damaging nerves that are in the close proximity of these veins.
In a series of 50 patients treated with EVLA for insufficient GSV above the knee, a technical success of 100% was reported after a median follow-up of 7 months, but this was accompanied by nerve damage in 8%. A recent study evaluating MOCA for the treatment of SSV reported an anatomical success of 96% without any nerve damage or other major complications. Therefore, MOCA could be an alternative for the treatment of various insufficient varicose vein segments without causing nerve damage.
The choice of treatment for patients with both above and below knee GSV insufficiency is nowadays only endovenous ablation of the above-knee segment. However, Theivacumar and co-workers recently showed that in these patients there is a significant residual reflux in approximately 41% of treated legs. These patients clearly showed less clinical improvement and approximately 90% of these patients needed additional treatment.
Up to now it is unknown whether treatment with MOCA can yield comparable results when used to treat insufficient GSV with diameters >= 12 mm, insufficient antero-lateral branches and insufficient GSV below the knee. The goal of this registry study is to provide insight in the safety and efficacy of

treatment of the above described insufficient varicose vein segments.

Study objective

The goal of this registry study is to provide insight in the safety and efficacy of treatment with MOCA for primary insufficiency of the GSV with a diameter >/=12mm, insufficient antero-lateral branches (<12 mm) and insifficincy of the GSV below the knee (<12mm).

Study design

The MOCA-XL study is a multicenter prospective registry study in the Rijnstate Hospital Arnhem and the Antonius Hospital Nieuwegein. In total 90 patients will be treated after they provided signed informed consent. Three different groups of patients will be included; 30 patients will be included with primary insufficiency of the GSV with diameters >/= 12 mm, 30 patients with insufficient antero-lateral branches (<12mm), and 30 patients with below-knee GSV insufficiency (<12mm).
Clinical state of patients will be evaluated using CEAP classification VCSS (Venous Clinical Severity Score) pre-treatment, and 4 weeks and 1 year after treatment to evaluate clinical success. Both visits are according to standard clinical care in both hospitals. During these visits an ultrasound scan will be performed to evaluate the technical success (to determine if the segments are still occluded). Patients will be asked to fill out the Aberdeen Varicose Vein Questionnaire and the RAND 36 short form questionnaire on these visits as well to evaluate disease specific and general health status. Finally, during procedure and until two weeks after treatment patients will be asked to report pain scores using the linear VAS score. If needed, patients can be additionally treated 6 weeks after MOCA, according to current standard care.

Intervention

Treatment with mechano-chemical ablation

Study burden and risks

Patients will be asked to fill out the Aberdeen Varicose Vein Questionnaire and the RAND 36 short form questionnaire pre-treatment, 4 weeks and 1 year after treatment. Additionally, they will be asked to report pain scores using the linear VAS score two weeks after treatment.(in total ca 40 minutes)
A possible risk of MOCA is allergy for the used sclerosans. The safety and efficacy of MOCA for the treatment of GSV (up to 12 mm in diameter) and SSV insufficiency was shown before, but remains to be evaluated for treatment of insufficiency of GSV >/= 12 mm, antero-lateral branches (<12mm) and GSV below the knee (<12mm) and long term results are unknown. The known side effects of other endovenous treatment modalities can also occur when patients are treated

using MOCA, such as bleeding from puncture site, infection of the puncture site, hematoma, and pain.

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. Symptomatic varicose veins, C3-C5
2. Ultrasound criteria:
a. Diameter supragenual great saphenous vein (GSV) >/= 12 mm , not tortuous; or
b. Insufficient antero-lateral branch <12 mm; or
c. Insufficient below knee GSV < 12 mm
3. Signed informed consent
4. Patient consents to follow-up

5. Age > 18 year en < 80 year

Exclusion criteria

1. Patient is not capable to provide informed consent
2. Pregnancy and lactation
3. C6 varicose veins
4. Previous surgery or endovenous ablation at to treated segment
5. Deep venous vein thrombosis in medical history
6. Oral anti-coagulant therapy
7. Contra-indications or allergy for sclerosant
8. Immobilisation
9. Coagulant disorders or increaased risk for thrombo-embolic complications: known coagulant disorders such as hemofilia A, hemofilia B, Von Willebrand disease, Glanzmann disease, factor VII-deficiency, idiopathic thrombo-cytopenic purpura, factor V Leiden disease and deep venous thrombosis or lung emboli in medical history
10. Fontaine III of IV peripheral arterial disease
11. Severe kidney disease: known GFR < 30 ml/min.
12. Liver diseases accompanied by changes in coagulation of the blood, anamnistic indications for tendency towards haemorrhage , such as epistaxis and spontanuous hematoma, known liver cirrhosis.

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):	20-12-2016
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Aethoxysclerol
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	aethoxysklerol
Generic name:	lauromacrogol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-10-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-10-2018
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
EudraCT	EUCTR2014-003341-10-NL
CCMO	NL47979.091.14