The ClariVein device using 2% and 3% liquid Polidocanol for the treatment of great saphenous vein incompetence

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

Summary

ID

NL-OMON39574

Source
ToetsingOnline

Brief title
ClariVein Polidocanol 2% vs 3% study

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym
great saphenous vein incompetence, varicose

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: industrie: Vascular Insights,Vascular Insights

Intervention

Keyword: clarivein, gsv, polidocanol

Outcome measures

Primary outcome

Our primary endpoint is the anatomical success rate of the treated GSV after 6 months, defined as occlusion confirmed by ultrasound of at least 85% which correlates to 25,5cm of the treated 30cm.

Secondary outcome

Mean VCSS change (evaluated at mentioned time points).

Pain score during procedure (VAS)

Two weeks post-preocedure pain score (VAS)

Health status (using the SF36 the general health status will be evaluated at mentioned time points).

Disease related quality of life (using the AVVQ, the quality of life related to the disease will be evaluated at mentioned time points).

Adverse events

Patient satisfaction measured in separate scores.

Study description

Background summary

The standard treatment for an incompetent great saphenous vein (GSV) is surgical stripping of the GSV combined with high ligation of the saphenofemoral junction. The prevalence of venous insufficiency in Europe and the United States is between 5 and 15 percent in men and between 15 and 30 percent in women. The severity of the disease varies from cosmetics objections to chronic venous insufficiency leading in 1% to ulcer formation with bad healing

tendencies. The treatment of trunk varicosity can be complemented with sclero-compression therapy or ambulant phlebectomy according to Muller for the remaining varicosis. In recent years, numerous minimal invasive therapies have been developed to treat GSV incompetence. These methods include sclero-compression, foam sclero-compression, laser and radio frequent ablation-therapy. These methods give better outcomes in terms of pain and return to normal activities, while the closure rate remains high compared to stripping of the vein. The surgical method is mostly performed under general anesthesia and the newer endogenous thermal methods under tumescent anesthesia. Perceived advantages over traditional surgery include fewer complications, minimal post procedural pain and faster recovery times. The use of minimal invasive methods increases steadily. ClariVein® is a new device for the treatment of GSV insufficiency. The technique uses a combination of chemical and mechanical components to assure long term closure of the insufficient GSV without needing any anesthesia.

Study objective

Our study tries to identify the ideal sclerosant dosage for the ClariVein® system in order to occlude the GSV permanently. By choosing the lowest dose with the same anatomical success rate, we achieve a safe treatment which also gives us the possibility to increase the maximum treatment length of the incompetent GSV. Our hypothesis is that there is no difference in outcome between patients having their incompetent GSV treated with ClariVein therapy using Polidocanol 2%, 3% liquid.

Study design

This prospective randomized controlled trial will be conducted in the Maastricht university hospital (MUMC+) and other clinics specialized in phlebology. All eight hospitals are located in the Netherlands. The MUMC+ will provide the trial coordinator, who manages the inclusion and randomization of patients in the MUMC+ and in each other center a dedicated coordinator will be appointed in the other clinics. Our research team will be completed with a project leader and an independent physician. 400 patients will be included in the study and divided equally over 2 groups. The patients will be randomized amongst the next groups: Group 1: ClariVein® simultaneous with 2% Polidocanol, Group 2: ClariVein® simultaneous with 3% Polidocanol. In each group 30cm of incompetent GSV will be treated with 5mL sclerosant. The treatment is limited due to the toxicity of Polidocanol which should not exceed more than 2mg per kg body weight per day.All patients are referred by the general practitioner for their symptoms of venous incompetence, e.g. varicose veins. At the first visit the patient is assessed for inclusion criteria by the physician. If the patient meets the inclusion criteria, they will be informed about the study and they are given the information brochure. The patient is explicitly told that they are able to withdraw from the study at any time for any reason without any

explanation and they will be guaranteed of the best medical care available. Computerized block randomization for allocation of treatment group which is stratified for centre, will take place after all inclusion and exclusion criteria have been verified and informed consent has been obtained. The result of the randomization is not mentioned to the patient to ensure blinding of the study. After randomization the patient will be scheduled for the treatment within 6 weeks.

Intervention

ClariVein liquid Polidocanol (2%,3%) procedure:
The patient will be examined by ultrasound to identify the GSV at the knee level. This will be done while the patient is standing. After the GSV is identified the patient will take place on the operating table and a Venflon needle will be inserted at knee level and a sheath will be introduced to ensure access for the ClariVein® system. The ball tip of ClariVein® system is placed 2cm distal to the saphenofemoral junction, measured from the hard shoulder of the saphenofemoral junction. The wire will be activated at the setting of 3500 rpm and after 3 seconds it will be moved distally at a steady pace of 1.0 - 2.0mm / second, 6 seconds per centimeter. With the rotating wire applying mechanical damage to the veinwall 5 mL Polidocanol is injected into the GSV. After 30 cm of the GSV is treated the system is removed from the vein.

Duplex ultrasonography will be performed after the procedure to visualize and quantify the spasm of the obliterated GSV segment and confirm patency of the deep venous system. Directly after the procedure a class 2 thigh stocking is applied to the leg for 48 hours and 2 weeks during daytime. There is no need for any form of anesthesia or analgesia during the procedure. Patients can resume their daily activities immediately. Because of the learning curve the physician operating the device has to acknowledge the performance of at least 10 procedures with ClariVein®, before treating patients in the study group. Training will be provided by Vascular Insights who will assist and train the physician for the first 10 ClariVein® treatments.

Study burden and risks

A possible drawback to this research is the extra time that is needed for completing questionnaires.

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) Patients who are first time treated for incompetence of the VSM, proven with duplex ultrasound examination.
2) CEAP classification C2-C4
3) All patients with informed consent.

Exclusion criteria

1) Age < 18 years and or incompetent.
2) Life expectancy of less than 6 months
3) Previous surgery for GSV incompetence
4) Occlusion of deep venous system
5) Pregnancy
6) No informed consent
7) Extreme obesity: BMI> 40
8) Very tortuous pace of GSV which bends at an angle of <90 º or more twists follow each other
9) Allergy or contraindication to Polidocanol

10) GSV diameter bigger than 12mm.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2012
Enrollment:	400
Type:	Actual

Medical products/devices used

Generic name:	ClariVein
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Polidocanol
Generic name:	Aethoxysklerol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	05-09-2011
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-02-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	30-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	14-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	15-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	18-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	03-08-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	21-06-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	19-09-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2013
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-003727-35-NL
CCMO	NL37769.068.11