

The ClariVein device using liquid Polidocanol and foam for the treatment of great saphenous vein incompetence : A dose finding study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26113

Source

Nationaal Trial Register

Brief title

ClariVein dose-finding study.

Health condition

Incompetence of the great saphenous vein

Varicose veins

ClariVein

Minimal invasive

Sponsors and support

Primary sponsor: academisch ziekenhuis maastricht (azM).

Source(s) of monetary or material Support: Vascular Insights

Intervention

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 24,5cm of the treated 30cm.

Secondary outcome

1. Mean VCSS change (evaluated at mentioned time points);
2. Pain score during procedure (VAS);
3. Two weeks post-precedure pain score (VAS);
4. Health status (using the SF36 the general health status will be evaluated at mentioned time points);
5. Disease related quality of life (using the AVVQ, the quality of life related to the disease will be evaluated at mentioned time points);
6. Adverse events;
7. Patient satisfaction measured in separate scores.

Study description

Background summary

Varicose veins due to incompetence of the Greater Saphenous Vein (GSV) are very common and are cause of many complaints. Treatment for an incompetent GSV is very common in the Netherlands in order to treat complaints and to prevent complications such as dermatoliposclerosis and ulcer formation. In the last years there are numerous new minimal invasive methods for closure of the GSV. Although Stripping is still considered the gold standard, the new minimal invasive methods are more commonly used. A new product has been introduced: The ClariVein® system. This minimal invasive procedure has the advantage over the other minimal invasive methods, that is does not require any form of tumescent anesthesia. The ClariVein® system makes use of a chemical and a mechanical component to occlude the GSV. The mechanical component damages the endothelium of the vein via a rotating wire. Yet, there is a choice of different sclerosant applications in order to achieve maximal endothelium damage. Our study tries to identify the best sclerosant dosage and form for the ClariVein® system in order to occlude the GSV permanently.

Only The Netherlands will be recruited.

Study objective

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 or 1% foam.

Study design

Follow-up will take place after 6 weeks and 6 months while history and quality of life questionnaires are conducted, physical examination and duplex scan are also performed.

Intervention

The procedure will be identical for every patient, except for the dosage and form of the chemical component. 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. Foam preparation: Foam will be made by the physician with 1 mL of 1% Polidocanol and 4 mL of room air in a 5mL Luerlock syringe that will be connected by a 3-way stop-cock with another 5mL Luerlock syringe according to the Tessari method (Figure 1). Through rapid alternating movements foam will be created before the wire is activated and pullback is started as the foam consistency.

Contacts

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Eligibility criteria

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 ° or more twists follow each other;
9. Allergy or contraindication to Polidocanol;

10. GSV bigger than 12mm.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion	
Date:	29-07-2011
Application type:	First submission

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
NTR-new	NL2866
NTR-old	NTR3009
Other	ABR : 37669
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A