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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26113

Bron
NTR

Verkorte titel
ClariVein dose-finding study.

Aandoening

Incompetence of the great saphenous vein
Varicose veins
ClariVein
Minimal invasive

Ondersteuning

Primaire sponsor: academisch ziekenhuis maastricht (azM).
Overige ondersteuning: Vascular Insights

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 bigger than 12mm.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2866

Register	ID
NTR-old	NTR3009
Ander register	ABR : 37669
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A