A multicenter, open-label, non-inferiority, randomized controlled trial comparing mechanochemical endovenous ablation using Flebogrif with endovenous laser ablation in the treatment of primary great saphenous vein incompetence.

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

Summary

ID

NL-OMON54246

Source
ToetsingOnline

Brief title
REBORN study

Condition

- Venous varices

Synonym
spider veins, Varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: Angiocare

Intervention

Keyword: Endovenous laser ablation, Flebogrif, Great saphenous vein incompetence, Mechanochemical endoveneus ablation

Outcome measures

Primary outcome

Primary outcomes is anatomical succes at 12 months.

Secondary outcome

Secondary outcomes are: intraprocedural pain, technical success, operation

time, postoperative pain, anatomical succes at 1, 6, 12, 24 and 60 month(s),

safety, complications, clinical success, quality of life, aesthetic result,

re-interventions and neo-reflux/vascularization.

Study description

Background summary

Chronic venous insufficiency (CVI) of the lower limbs is a common disorder with a prevalence of superficial vein reflux of 21% in the adult population, which increases linearly with age. CVI is generally caused by insufficiency of the great saphenous vein (GSV). Minimally invasive endothermal treatment, for example, endovenous laser ablation (EVLA) or radiofrequency (RFA), has become the first line of treatment for superficial venous reflux. However, the use of endothermal ablation techniques is associated with the thermal damage to superficial nerves, skin burn, prolonged pain, and tumescent anesthesia can also be painful. Newer treatments, especially non-thermal ablation, have potential benefits both for patient acceptability and decreased risk of nerve injury. For example, mechanochemical endovenous ablation (MOCA), which combines

mechanical endothelial damage with the infusion of sclerosant foam injection. Fleblogrif (Balton, Poland) is a relatively new MOCA device. The expectation is that compared to EVLA treatment with Flebogrif is less painful and leads to faster recovery.

Study objective

The current study has been designed to demonstrate that MOCA using Flebogrif is not inferior to EVLA for the treatment of GSV insufficiency.

Study design

Multicenter, open-label, non-inferiority, randomized controlled trial.

Intervention

The intervention group will receive treatment with MOCA using Flebogrif. The control group will receive treatment with EVLA. Patients will be randomized to either one of the two treatment arms.

Study burden and risks

Patients included in the control group do not directly benefit from participation in this study. Patients included in the intervention group might benefit from treatment with Flebogrif. The expected benefit is less pain during and after treatment resulting in earlier return to daily activity or work. Additional risk or side effects from Flebogrif are transient migraine and allergic reaction on Polidocanol (see the structured risk analysis in Chapter 13). The extra burden for all participants of the study consists of five extra follow-up visits to the outpatient clinic, physical examinations and duplex ultrasounds of the treated leg, quality of life questionnaires, aesthetic scores, and daily pain scores during one week.

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. Age 18-80 years
2. Unilateral symptomatic primary GSV and SFJ incompetence
3. GSV diameter >= 4 or <= 12 mm
4. GSV treatment length >= 15 cm

Exclusion criteria

1. Bilateral endovenous thermal/MOCA treatment of the GSV
2. Simultaneous ipsilateral endovenous thermal-/MOCA treatment of additional veins
3. C6 varicose veins
4. Previous ipsilateral GSV or AASV treatment
5. Superficial thrombophlebitis or deep venous thrombosis in the last 6 months
6. Occlusion of deep venous system
7. Coagulation disorders or increased risk of thromboembolism
8. Direct oral anticoagulants or vitamin K antagonists
9. Pregnancy or lactation
10. Immobilization
11. Cognitive impairment or language barrier
12. Allergy or contraindication to Polidocanol
13. Severe renal or liver insufficiency

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2021
Enrollment:	310
Type:	Actual

Medical products/devices used

Generic name:	Flebogrif
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2023
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 25145
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74491.029.20
OMON	NL-OMON25145