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

Published: 09-02-2021
Last updated: 15-05-2024

MOCA using Flebogrif is not inferior to EVLA for the treatment of GSV insufficiency.

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

Summary

ID

NL-OMON25145

Source
NTR

Brief title
The REBORN study

Condition

- Venous varices

Synonym
GSV incompetence

Health condition

Great spahenous vein incompetence

Research involving
Human

Sponsors and support

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

Intervention

- Medical device

Explanation

Outcome measures

Secondary outcome

 Technical success Operation time Postprocedural pain Complications Clinical success Time to return to work Disease-specific quality of life Aesthetic result

Study description

Background summary

Endovenous laser ablation (EVLA) is associated with an excellent outcome in the treatment of great saphenous vein incompetence (GSV). However, the use of thermal ablation requires tumescence anesthesia and is associated with risk of thermal damage. Mechanochemical endovenous ablation (MOCA) is a non-thermal ablation alternative which combines mechanical endothelial damage with the infusion of sclerosant foam injection. Tumescence anesthesia is not required. Preliminary experiences with MOCA using the Clarivein device showed less intraprocedural and postprocedural pain and a faster clinical improvement. Flebogrif is a relatively new MOCA device. To determine the role of MOCA using Flebogrif in the treatment of primary great saphenous vein incompetence, a well-designed randomized controlled clinical trial of sufficient sample size is required.

Study objective

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

Flebogrif vs EVLA

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Age 18-80 years
- Unilateral symptomatic primary GSV and saphenofemoral junction (SFJ) incompetence
- GSV diameter ≥ 4 or ≤ 12 mm
- Intrafascial GSV length ≥ 15 cm

Exclusion criteria

- Bilateral endovenous thermal-/MOCA treatment of the GSV
- Simultaneous ipsilateral endovenous thermal-/MOCA treatment of additional veins
- C6 varicose veins
- Previous ipsilateral GSV or anterior accessory saphenous vein treatment
- Superficial thrombophlebitis or deep venous thrombosis in the last 6 months
- Occlusion of deep venous system
- Coagulation disorders or increased risk of thromboembolism
- Use of direct oral anticoagulants or vitamin K antagonists
- Pregnancy or lactation
- Immobilization
- Cognitive impairment or language barrier
- Allergy or contraindication to Polidocanol
- Severe renal or liver insufficiency

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:	Recruiting
Start date (anticipated):	24-09-2021
Enrollment:	320

Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 54246
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9527

Register	ID
CCMO	NL74491.029.20
OMON	NL-OMON54246

Study results