Beoordeling van mechanochemische endoveneuze behandeling in vergelijking met radiofrequente behandeling van spataderlijden ten gevolge van insufficientie van de vena saphena parva. Onderzoek in meerdere ziekenhuizen en in opzet van gerandomiseerde studie.

No registrations found.

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

Summary

ID

NL-OMON26692

Source
Nationaal Trial Register

Brief title
MESSI

Health condition

Symptomatic venous insufficiency of the small saphenous vein. Comparison of two endovenous treatment modalities.

Spataderlijden ten gevolge van insufficientie van de vena saphena parva. Beoordeling van tweetal endoveneuze behandelingen.

Keywords:
small saphenous vein (SSV)
varicose veins
polidocanol

clarivein

Trefwoorden
vena saphena parva (VSP)
spataderen
polidocanol
clarivein

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis Nieuwegein afd Heelkunde
Rijnstate Ziekenhuis Arnhem afd Heelkunde
Source(s) of monetary or material Support: Stichting Varysta

Intervention

Outcome measures

Primary outcome

Anatomical success (at one year follow up) proven by duplex ultrasound.

Secondary outcome

Initial technical success

Pain during and post treatment

Study description

Background summary

SUMMARY

Rationale: In the last decade the treatment of varicose veins endovenous thermal ablation became the gold standard. Although the anatomical success is excellent, major downsides to thermal ablation are pain and nervous injury. Especially in SSV the risk of nervous injury is significant.The novel MOCA treatment is developed to minimize pain and additional injury in ablation. This technique is based on combining mechanical injury to the intima with sclerotherapy. The MESSI study is designed to evaluate MOCA in SSV.

Objective: To evaluate the anatomical success of MOCA versus RFA in treatment of symptomatic insufficient SSV.

Study design: multicentre randomised controlled intervention study.

Study population: 160 patients with symptomatic insufficiency of SSV, 18-80 years, signed informed consent.

Intervention: Group 1: mechanochemical endovenous ablation (ClariVein - catheter). Group 2: endovenous radiofrequency ablation (VNUS ClosureFast catheter).

Main study parameters/endpoints: Primary study parameter is anatomical success rate at one year follow up. Secondary parameters: pain, initial technical success, clinical success, complications and length of procedure.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both intervention modalities are accepted, frequently used and safe. The burden of participation consists of 3 additional out-patient consultations, including duplex, and the use of questionnaires.

Study objective

Treatment of small saphenous vein incompetence with MOCATM is associated with anatomical success not inferior to radiofrequency ablation.

Study design

before treatment baseline

treatment

4 weeks follow up

1 year follow up

2 years follow up

5 years follow up

Intervention

Endovenous ablation of insufficient small saphenous veins by mechanochemical ablation using ClariVein versus radiofrequency ablation by ClosureFast.

Contacts

Public

Sint Antonius Ziekenhuis
Doeke Boersma
Nieuwegein
The Netherlands
0031 30 609 2052
Scientific
Sint Antonius Ziekenhuis
Doeke Boersma
Nieuwegein
The Netherlands
0031 30 609 2052

Eligibility criteria

Inclusion criteria

1. Primary SSV incompetence 2. Symptomatic varicose veins, C1-C5 3. Duplex ultrasound criteria meet criteria for general endovenous treatment: diameter of small saphenous vein > 3 mm and < 12 mm, non-tortuous 4. Signed informed consent 5. Patient is willing to participate in follow up 6. Age> 18 year and < 80 year

1. Primaire insufficientie van de VSP 2. symptomatische varices, C1-C5 3. diameter VSP 3-12 mm en niet gekronkeld verloop 4. getekende informer consent 5. bereidheid tot deelnemen follow up. 6. leeftijd 18 tot 80 jaar

Exclusion criteria

1. Patient is incapable of informed consent 2. Pregnancy and lactation 3. C6 varicose veins 4. Pervious surgical or endovenous treatment of the affected vein 5. History of deep venous thrombosis in the affected leg 6. Oral anticoagulants 7. Contraindication or known allergy to sclerosans 8. Immobilization 9. Coagulation disorders or increased risk of thrombo-embolic complications: known coagulation disorders as hemophilia A, hemophilia B, Von Willebrandt disease, Glanzmann disease, factor VII-deficiency, idiopathic trombocytopenic purpura, factor V Leiden, deep venous thrombosis or pulmonary embolism in medical history 10. Fontaine III of IV peripheral arterial disease 11. Severe renal insufficiency: known glomerular filtration rate < 30 mL/min 12. Liver disease, associated with changes in coagulation, anemnestic evidence of bleeding as epistaxis and spontaneous hematoma, liver cirrhosis.

1. Patiënt niet in staat tot geven informed consent 2. Zwangerschap of borstvoeding 3. C6 varices 4. Eerdere behandeling aangedane vene dmv chirurgie of endoveneuze therapie. 5. Diep veneuze thrombose in het aangedane been 6. Orale anticoagulantia 7. Contraindicatie of bekende allergie for polidocanol 8. Immobilisatie 9. Stollingstoornissen of verhoogd risico op trombo-embolische complicaties: hemofilie A of B, Ziekte van Von Willebrandt, ziekte van Glanzmann, factor VII- deficiëntie, idiopathische trombocytopenische purpura, factor V Leiden, DVT or long-embolieën in voorgeschiedenis. 10. Perifeer arterieel vaatlijden (fontaine III - IV) 11. Ernstige nierinsufficientie (eGFR <30ml/min) 13. Leverziekten, welke leiden tot stollinsveranderingen en levercirrhose

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2014
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40762
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4480
NTR-old	NTR4613
CCMO	NL42781.100.13
OMON	NL-OMON40762

Study results

Summary results

1. Elias S, Raines JK.Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. Phlebology. 2012;27:67-72.
2. Van Eekeren RRJP, Boersma D, Elias S, Holewijn S, Werson DAB, De Vries JPPM, Reijnen MMJP. Mechanochemical endovenous ablation of great saphenous vein incompetence using the ClariVein® device: a safety study. J Endovasc Ther. 2011;18:328-334
3. Boersma D, Van Eekeren RRJP, Werson DAB, De Vries JPPM, Reijnen MMJP. Mechanochemical endovenous ablation of small saphenous vein insufficiency using the ClariVein® device: One-year results of a prospective series. EJVES 2013;45(3): 299-303
4. Bishawi M, Bernstein R, Boter M, Draugh D, Gould C, Hamilton C, Koziarski J. Mechanochemical ablation in patients with chronic venous disease: a prospective multicenter report. Phlebology. 2013; Epub ahead of print