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.

Gepubliceerd: 28-05-2014 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26692

Bron
NTR

Verkorte titel
MESSI

Aandoening

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

Ondersteuning

Primaire sponsor: St. Antonius Ziekenhuis Nieuwegein afd Heelkunde
Rijnstate Ziekenhuis Arnhem afd Heelkunde
Overige ondersteuning: Stichting Varysta

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

before treatment baseline

treatment

4 weeks follow up

1 year follow up

2 years follow up

5 years follow up

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Sint Antonius Ziekenhuis

Doeke Boersma
Nieuwegein
The Netherlands
0031 30 609 2052

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40762
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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