

VARICO 2 TRIAL: Prospective randomised trial analyzing results after Radiofrequency Obliteration VNUS ClosureFAST and Endovenous Laser Ablation ELVeS Radial Fiber 1470nm using local tumescent anaesthesia for great saphenous vein incompetence.

Gepubliceerd: 13-04-2011 Laatste bijgewerkt: 13-12-2022

Higher occlusion rate in the EVLA group seen at 1 week postoperative. More recurrences seen in the VNUS group seen at long term. No differences in short term recovery results between both groups.

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

Samenvatting

ID

NL-OMON21594

Bron

NTR

Verkorte titel

N/A

Aandoening

Recovery, complications, Quality of Life, pain, occlusion- and recurrence rate, tumescent anaesthesia.

Herstel, complicaties, kwaliteit van leven, pijn, herontstaan spataderen na behandeling, tumescentie.

Ondersteuning

Primaire sponsor: Ab Aquapendente Research

Overige ondersteuning: Ab Aquapendente Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Occlusion- and recurrence rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Early varicose veins are relatively benign but some patients will progress to develop severe problems, including venous ulcers. Endovenous treatments like VNUS-ClosureFAST and Endovenous Laser Ablation are promising procedures for the treatment of trunk vein incompetence. Post operative these treatments give less complications and a better quality of life compared to surgery as stripping. Occlusion - and recurrences rate seen on short and long term is our main outcome parameter. We hypothesize that occlusion rate will be higher in the EVLA group and recurrence rate will be higher in de VNUS group. There will be no difference in quality of life after both treatments.

Doel van het onderzoek

Higher occlusion rate in the EVLA group seen at 1 week postoperative. More recurrences seen in the VNUS group seen at long term. No differences in short term recovery results between both groups.

Onderzoeksopzet

1. 1 week occlusion;
2. Two weeks recovery;
3. Every year recurrence rate, till 5 year after the treatments.

For the measurements VAS-scores are used and questionnaires as the euroqual 5.

Onderzoeksproduct en/of interventie

1. Endovenous Laser Ablation 1470 nm RADIAL fiber;
2. VNUS ClosureFAST.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Incompetence of great saphenous vein, (reflux >0,5 seconds);
2. Length of treated vein >15 cm;
3. Diam; >0,3 cm and <1,5 cm;
4. Age >18 year;
5. No primary treatment;

6. CEAP equal or greater than 2;
7. Informed consent procedure.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Primary treatment of great saphenous vein incompetence;
2. Pregnancy;
3. Immobility;
4. Pathology, not willing/able to have local tumescent anaesthesia;
5. Hypersensitivity for lidocain;
6. Flebitis in time of surgery;
7. Serpentin-like veins.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	12-01-2011
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 13-04-2011

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	NL2716
NTR-old	NTR2854
Ander register	METC VUmc : 2011/125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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Menno T. W. Gaastra, MD,^a Marco J. Tangelder, MD, PhD,^b and Michael C. Mooij, MD.

Prospective comparative cohort study evaluating incompetent great saphenous vein closure using radiofrequency-powered segmental ablation or

1470-nm endovenous laser ablation with radial-tip

fibers (Varico 2 study). Journal of Vascular Surgery: Venous and Lymphatic Disorders. January 2018. Volume 6, Number 1: 31-40.