

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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21594

Source

NTR

Brief title

N/A

Health condition

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

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

Sponsors and support

Primary sponsor: Ab Aquapendente Research

Source(s) of monetary or material Support: Ab Aquapendente Research

Intervention

Outcome measures

Primary outcome

Occlusion- and recurrence rate.

Secondary outcome

1. Quality of Life;
2. Complications;
3. Pain.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2011
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion	
Date:	13-04-2011

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2716
NTR-old	NTR2854
Other	METC VUmc : 2011/125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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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.