

VARICO TRIAL, Prospective randomised trial to analyse short and long term results of stripping versus endovenous laser treatment of long saphenous vein incompetence under local anaesthesia.

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The recurrence risk after endovenous laser treatment is less than after stripping of the long saphenous vein performed under local anaesthesia.

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

Samenvatting

ID

NL-OMON25507

Bron

NTR

Verkorte titel

N/A

Aandoening

Recurrence of varicosis.

Endovenous laser technique versus stripping

Local anaesthesia

Treatment of the long saphenous vein incompetence

Ondersteuning

Primaire sponsor: Ab Aquapendente Research

Koninginneweg 9

1217 KP Hilversum

Overige ondersteuning: Ab Aquapendente Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint is the recurrence rate of the varicose vein.

Toelichting onderzoek

Achtergrond van het onderzoek

Early veins are relatively benign, but some patients will progress to develop severe and irreversible problems of chronic venous insufficiency, including venous ulcers. Surgery, by high ligation and stripping of trunk veins, is still considered the "gold standard" for treatment of varicose veins in association with trunk incompetence.

Recently, the endovenous laser treatment is introduced. The promising treatment reports less recurrences, complications and a better quality of life. In this study we will compare the postoperative results of endovenous laser treatment with the traditional stripping procedure, performed under local anaesthesia.

Doel van het onderzoek

The recurrence risk after endovenous laser treatment is less than after stripping of the long saphenous vein performed under local anaesthesia.

Onderzoeksopzet

Recurrence of varicose vein can be diagnosed from 6 month till several years after operations. Interim analyse will be done from 1 year till 10 years after the operation.

Onderzoeksproduct en/of interventie

- Stripping method
- Endovenous laser therapy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Long saphenous vein (LSV) incompetence (duplex: reflux > 0,5 sec. measured and seen in standing position by manual compression or valsalva manoeuvre)
2. Diameter of LSV equal or more than 0,3 cm and equal or less than 1,5 cm
3. Length of LSV traject more than 15 cm intrafascial
4. No earlier operations
5. Age between 18-70 years
6. CEAP classification equal or more than C2
7. Informed consent

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Patient does not meet the therefore mentioned inclusion criteria
2. Pregnancy
3. Immobility
4. Pathology deep venous system
5. Patients don't wish to be operated under local anaesthesia
6. Proven reaction on lidocaine
7. Contra indications to stop Clopidogrel or coumarine or that can not be stopped or temporarily replaced by fraxiparine
8. Flebitis in time of surgery

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	25-02-2008
Aantal proefpersonen:	274
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 04-03-2008

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	NL1198
NTR-old	NTR1243
Ander register	: 12256.049.07
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

Eur J Vasc Endovasc Surg. 2010 Nov;40(5):649-56.

Randomised controlled trial comparing sapheno-femoral ligation and stripping of the great saphenous vein with endovenous laser ablation (980 nm) using local tumescent anaesthesia: one year results.

Pronk P, Gauw SA, Mooij MC, Gastra MT, Lawson JA, van Goethem AR, van Vlijmen-van Keulen CJ.

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Stefanie A. Gauw, CRC, James A. Lawson, MD, PhD, Clarissa J. van Vlijmen-van Keulen, MD, PhD, Pascal Pronk, MD, Menno T. W. Gaastra, MD, and Michael C. Mooij, MD. Five-year follow-up of a randomized, controlled trial comparing saphenofemoral ligation and stripping of the great saphenous vein with endovenous laser ablation (980 nm) using local tumescent anesthesia. *Journal of vascular surgery*. February 2016. Volume 63, Number 2: 420-428