

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.

No registrations found.

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

Summary

ID

NL-OMON25507

Source

NTR

Brief title

N/A

Health condition

Recurrence of varicosis.
Endovenous laser technique versus stripping
Local anaesthesia
Treatment of the long saphenous vein incompetence

Sponsors and support

Primary sponsor: Ab Aquapendente Research

Koninginneweg 9
1217 KP Hilversum

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

Koninginneweg 9
1217 KP Hilversum

Intervention

Outcome measures

Primary outcome

Primary endpoint is the recurrence rate of the varicose vein.

Secondary outcome

Secondary endpoints are complications and quality of life.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

- Stripping method
- Endovenous laser therapy

Contacts

Public

R. Pullens
Comeniusstraat 3
Alkmaar 1817MS
The Netherlands
072-5157744

Scientific

R. Pullens
Comeniusstraat 3
Alkmaar 1817MS
The Netherlands
072-5157744

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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):	25-02-2008
Enrollment:	274
Type:	Actual

Ethics review

Positive opinion	
Date:	04-03-2008
Application type:	First submission

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

Study results

Summary results

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, Gaastra MT, Lawson JA, van Goethem AR, van Vlijmen-van Keulen CJ.

Flebologisch Centrum Oosterwal, Overkrocht 10, 1815 KX Alkmaar, The Netherlands.
pascalpronk888@hotmail.com.

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:

