Analysis of short and long term results of stripping versus endovenous laser treatment for long saphenous vein incompetence under local anaesthesia.

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Analysis of short and long term results of stripping and endovenous laser treatment for long saphenous vein incompetence under local anaesthesia.Endpoint is the recurrence rate of the varicose vein, secondary endpoints are pain, complications,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON30581

Source
ToetsingOnline

Brief title
Stripping versus endovenous laser treatment for varicosis

Condition

- Venous varices

Synonym
long saphenous vein incompetence, varices

Research involving
Human

Sponsors and support

Primary sponsor: Ab Aquapendente Research B.V.

Source(s) of monetary or material Support: Extra kosten;zoals controlebezoeken en reiskosten na één jaar worden bekostigd uit eigen middelen.

Intervention

Keyword: endovenous laser treatment, local anaesthesia, Long saphenous vein, stripping

Outcome measures

Primary outcome

Primary study parameter: recurrence rate of varicose veins in the operated

area.

Secondary outcome

Secondary study parameters: pain, satisfaction, quality of life and

complications and cost-effectiveness analises.

Study description

Background summary

Varicose veins are a common problem in both men and women. The prevalence increases with age. In almost one third of the adult population varicosity is present. The aetiology is most due to genetic risk factors and age.
Early varicose 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 'old standard' for treatment of varicose veins in association with trunk vein incompetence. Recently, the endovenous laser treatment is introduced. This promising treatment reports less recurrences, complications and better quality of life.

Our institute is specialised in treating lower extremity superficial venous insufficiency.
In this study we will compare the postoperative results of the endovenous laser treatment with the traditional stripping procedure, performed under local anaesthesia.

Study objective

Analysis of short and long term results of stripping and endovenous laser treatment for long saphenous vein incompetence under local anaesthesia. Endpoint is the recurrence rate of the varicose vein, secondary endpoints are pain, complications, satisfaction and quality of life and profit costs analises.

Study design

The aim of this randomized prospective intervention study is to compare two methods of treatment (stripping versus endovenous laser treatment for long saphenous vein incompetence) and the postoperative results during a follow up of 10 years.
By using the ultrasound, the diagnosis insufficiency of the long saphenous vein will be determinated. If an operation is needed the treatment options will be discussed with the patient. The operation will be performed under local anesthesia. Check ups will take place after 1 and 6 weeks and 6 and 12 months, as we are used to do. More check ups will take place once a year during the following 9 years. During the check- up we will perform an ultrasound and ask the patient to fill out a questionnaire (EuroQuol5: quality of life and registration of complications, last questionnaire at 6 months)

Intervention

One group of the patients with an incompetence of the long saphenous vein (LSV) are treated with surgical ligation and stripping of the LSV. The other group will be treated with the endovenous laser technique. Both procedures are performed under local anaesthesia and after the operation all patients will be treated with sclerotherapy and elastic compression bandage.

Study burden and risks

Postulation of the indication for operation, the operation and the postoperative check-ups up to one year is what we are used to do in every operated patient in our institute. Extra check-ups for 9 years will take place after the first year. Ultrasound investigation (a non-invasive investigation) and the questionnaires that have to be filled out during the first 3 check-ups are not aggravating.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Incompetence of the long saphenous vein

Exclusion criteria

pregnancy
immobile patient

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2008
Enrollment:	274
Type:	Actual

Ethics review

Approved WMO

Date:	25-02-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL12256.094.07