A randomized controlled multicenter trial comparing modern great saphenous vein stripping with crossectomy, with modern great saphenous vein stripping without crossectomy and radiofrequency ablation for primary great saphenous vein incompetence (STRIP trial).

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35873

Source
ToetsingOnline

Brief title
STRIP trial

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym

Chronic venous insufficiency, varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium Medisch Centrum Parkstad;Maatschap Chirurgie

Intervention

Keyword: crossectomy, great saphenous vein, modern stripping, radiofrequency ablation

Outcome measures

Primary outcome

The primary studyparameter will be a clinical recurrence measured by duplex echography at 3,12 and 24 months after intervention.

Secondary outcome

Secondary study parameters will be quality of life as measured by different questionnaires. This study will use the SF-36, EuroQol-5, Aberdeen varicose Vein Questionnaire (AVVQ) and the Pain Disability Index for measuring quality of life. Questionnaires will be completed before and 1, 3, 12, 24 months after intervention. Another secondary parameter which will be evaluated is the cost of the intervention.

Study description

Background summary

Chronic venous insufficiency (CVI) of the lower extremities is a common disorder and occurs in 15% of men and 35% of women (1-3 Callam, Evans, Margolis). The effect of venous insufficiency on quality of life is substantial and comparable to chronic diseases such as arthritis, diabetes and

cardiovascular diseases (4 Andreozzi). The venous ulcer of the lower extremities has a prevelence of 1% (5 Nelzen). The medical costs of CVI are high. Almost 2% of England's medical costs are due to CVI. The signs and symptoms of venous disease cause a decline in patients quality of life and account for a high level of absenteeism. Recently it was shown that in standing professions venous symptoms occur in more than 80% of workers. In 7% of the cases this led to absenteeism (6 Krijnen). The gold standard for treatment of CVI of the greater saphenous vein (GSV) is the so-called stripping of the veins (7 Bos). In recent years, however, new techniques are developed and existing techniques have been further developed in the treatment of CVI of the GSV. The preferred treatment of CVI of the GSV is open for discussion ever since.

Study objective

To date, all studies evaluating minimally invasive interventions for treatment of venous insufficiency of the GSV have been comparing the techniques to the traditional method of stripping (under spinal or general anesthesia, without using duplex imaging, with a success rate of 70-78% after 1 -3 Years) (7 Bos). When the stripping is preformed by means of duplex imaging and local, tumescent anesthesia, a significantly higher success rate of 90-98% is achieved after 6-12 months (15 Rasmussen). The available studies of the modern stripping and minimally invasive techniques for the treatment of CVI of the VSM are small. Sufficient long follow-up to illustrate superiority of one of the techniques is lacking. Also, most techniques are evaluated only by clinical recurrence measured with duplex echography and rarely by means of changes in patients quality of life. Until now, it is unclear which is the most succesful intervention in treating venous insufficiency of the GSV. This research will answer this question by comparing head to head two of the most widely used modern techniques in a prospective randomized study.

Study design

Prospective, randomized non-blinded, multicenter intervention study in which three are already widely used techniques (modern stripping with crossectomy, modern stripping without crossectomy and radiofrequency ablation) are compared in terms of recurrence, quality of life and cost effectiveness for two years.

Intervention

Patients will be enrolled in the outpatient clinic for vascular surgery. Participating patients diagnosed with venous insuffiency of the GSV according to the CEAP classification (appendix protocol) will be randomised in one of three intervention groups (modern stripping with crossectomy, modern stripping without crossectomy and radiofrequency ablation). Modern stripping is preformed under local, tumescent anesthesia. The saphenofemoral junction will be searched

by duplex, so the incision and dissection to a minimum. The GSV will be approched and stripped via a small incision in the groin. By using modern stripping equipment, a second incision at knee level is abbandoned. The optional crossectomy will be standardized. The third minimally invasive intervention will be conducted with the VNUS ClosureFAST* Catheter without an incision in the groin. The VNUS ClosureFAST* catheter for the treatment of venous reflux delivers radiofrequency energy to a heating element to heat and contract the collagen within the vein walls and cause the shrinkage and collapse of the vessel.

Study burden and risks

The research will have little effect on the participants. Patients will recieve one of two already wideley used treatments for treating venous insufficiency of the GSV. After the intervention patients will enter a non-invasive follow-up consisting of duplex examinations and completing questionnaires at fixed intervals.

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

-Patients with primary varicosity of the GSV, between age 18-80 year.
-CEAP 2-4(Appendix B/VI), without deep vein insufficiency.
-Minimum distance between skin and the GSV in the first 20 cm from the SFJ >5mm.
-Minimum length of to be treated GSV 10cm.
-GSV on one side will be treated in the case of bilateral insufficiency.
-GSV will be treated only in the case of solitary GSV insufficiency.
-Patients treated by experienced surgeon/center.

Exclusion criteria

-Age <18 years or >80 years.
-Deep vein insufficiency in the same extremity (duplex verified).
-Previous thrombosis of the affected limb (secondary thrombosis)
-Tortuosity of the GSV, double GSV system.
-Superficial veins with a distance of <5mm to the skin surface (RF cannot be applied), as measured at echo-duplex.
-Patients with double GSV's and/or lateral accessory insufficient branch.
-Earlier operation of the GSV with crossectomy/stripping(recurrency).
-Operated for small saphenous vein (SSV) incompetence the last 3 months.
-Known ABI <0,9 or history of intermittent claudication or peripheral pulselessness (clinical examination)in either extremity.
-Patients with active malignancy.
-Patients with other known medical condition that contradict any of the treatments in the study.
-History of CVA/central nervous system disease
-Pregnancy
-Patients treated with coumarine derivates, if cannot be interrupted during treatment(switched to a LMWH).
-Pacemaker

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2011
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-09-2011
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL36200.096.11