Minimal invasive treatment of varicose veins

Published: 15-10-2010
Last updated: 04-05-2024

Comparing the gold standard of surgical stripping with the minimal invasive treatment options: laser and VNUS (radiofrequency ablation)

Ethical review	Approved WMO
Status	Will not start
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON32684

Source
ToetsingOnline

Brief title
Berger I study

Condition

- Venous varices

Synonym
Varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Invasive, Minimal, Varicose, Veins

Outcome measures

Primary outcome

- Duplex recurrence

- Clinical recurrence

- Success of treatment

Secondary outcome

- Time until return to work

- Quality of life

Study description

Background summary

Minimal invasive varicose vein treatment options are rapidly being introduced as alternative for the surgical strip. Up till now no level 1 evidence has been obtained to justify one of those minimal invasive treatment options as a serious alternative for the surgical strip

Study objective

Comparing the gold standard of surgical stripping with the minimal invasive treatment options: laser and VNUS (radiofrequency ablation)

Study design

Open, randomized clinical trial

Intervention

Group 1: conventional surgical stripping

Group 2: radiofrequency ablation

Group 3: laser ablation

Study burden and risks

All treatment options are proven safe and will cause no additional harm.
Stripping causes a scar in the groin which will not be made in case of laser / VNUS

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

Older than 17 years
Ambulant patient
ASA 1 or 2
Open deep venous system
Primary varicose veins

Exclusion criteria

Extensive tortuosity
Previous deep venous thrombosis
Pregnant/ breastfeeding woman
No informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	330
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL30284.091.09