A comparison of two anesthetic techniques for VNUS closureFAST procedure: local or locoregional

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Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON33088

Source
ToetsingOnline

Brief title
anesthesia for VNUS closureFAST procedure

Condition

- Vascular therapeutic procedures
- Venous varices

Synonym
varicose veins, varicosis

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: mogelijk kleine bijdrage van

opleidingscentrum Diakonessenhuis Utrecht

Intervention

Keyword: local anesthesia, locoregional anesthesia, pain, VNUS closure

Outcome measures

Primary outcome

Primary outcome: pain during the VNUS closureFAST procedure, measured as a

numerric score of the mean pain during the procedure.

Secondary outcome

Secundary outcomes:

* Patiënt satisfaction

* Postoperative pain

* (prolonged) block at the time of discharge after locoregional anesthesia

* Duration of the procedure excluding anesthesia and including anesthesia

* Duration of hospital admission, possible extended admission time

* Satisfaction surgeon

* Complications:

* Toxicity (systemic)

* Nerve damage (by locoregional block, local anesthesia/compression, surgery)

* Burns

* Postoperative bleeding

* Failed procedure, surgical

* Failed block

Study description

Background summary

Varicosis is a common ailment. The VNUS closureFAST procedure (FDA approved 1999) is an alternative to traditional stripping of the insufficient VSM. This endovascular radiofrequent ablation is accepted as a good alternative to conventional surgery. The procedure can be carried out under local or locoregional anesthesia. To date, no research has been done into which anesthesia technique is most suitable.

Study objective

This study aims to show by which technique the patient feels the least pain. It is also designed to show which advantages and disadvantages are linked to the abovementioned forms of anesthesia and if there are differences in postoperative pain experiences. From this a conclusion can be made as to which form of anesthesia is preferential for the VNUS closureFAST procedure.

Study design

Randomized Controled Trial. After the patients have given informed consent and are included in the trial, they will be randomized in two groups. One group will receive local anesthesie, the other group locoregional anesthesia.

Study burden and risks

The patient will not be exposed to any extra risks than during the current standard treatment. At this moment both anesthesia techniques are used. The patient must be prepared to answer some questions regarding pain and satisfaction.

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

- All single sided VNUS closureFAST procedures, without convolutectomy
- informed consent
- CEAP-classification 2 and 3
- duplex ultrasound confirmed varicosis
- age * 18 years old
- good comprehension of the dutch language

Exclusion criteria

- VNUS closureFAST procedure both sides
- pre-existent neurological damage or - disabilities of the leg
- contra-indications for VNUS closureFAST procedure: recidive varicosis, lumen of the vein to wide, very twisting vein, to many convolutes.
- contra-indication for local or locoregional anesthesia: over-sensitiveness for lidocain and/or mepivacain
- preference for general anesthesia
- legally incapable

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	110
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-09-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL26394.100.09