A randomized controlled trial for Local Tumescent anesthesia with phlebectomy according to the Muller method.

No registrations found.

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

Summary

ID

NL-OMON26677

Source
NTR

Brief title
LTAF

Health condition

Varicose veins
Varices
Tumescent anesthesia
Sodium bicarbonate

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Per- and postoperative pain

Secondary outcome

complications
time to full recovery/functionality
cost reduction.

Study description

Background summary

The aim of this randomised controlled trial is to compare if adding sodium bicarbonate 1.4% to lidocain chloorhydrate 1% and epinifrine 0.9% results in significant less per-and postoperative pain in comparison with the routine LTA epinifrine 0.9% and lidocain chloorhydrate 1% in ambulant phlebectomy according to the Muller Method. Secondary outcomes are complications, time to full recovery/functionality and cost reduction.

Study objective

The aim of this randomised controlled trial is to compare if adding sodium bicarbonate 1.4% to lidocain chloorhydrate 1% and epinifrine 0.9% results in significant less per-and postoperative pain in comparison with the routine LTA epinifrine 0.9% and lidocain chloorhydrate 1% in ambulant phlebectomy according to the Muller Method.

Study design

Per-operative
2 hours postoperative
1 day postoperative
2 days postoperative
7 days postoperative
14 days postoperative

Intervention

Intevention: lidocaïne chloorhydrate 1% with epinephrine in natriumbicarbonate1.4%
Control: standard LTA (lidocaïne chloorhydrate 1% with epinephrine in normal saline 0.9%

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Eligibility criteria

Inclusion criteria

Older than 18 years
Indication for Muller Phlebectomy according to the CEAP classification

Exclusion criteria

allergy to anesthesia
acute diseases
chronic kidney- or liver failure
analgetics treatment
treatment with monoamine oxidase inhibitors or tricyclic antidepressants
psychiatric illness according to the DSM-IV classification criteria
alcohol abuses

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	110
Type:	Actual

Ethics review

Positive opinion

Date:	17-04-2014
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	NL4337
NTR-old	NTR4534
Other	METC : 12-T-77

Study results

Summary results
None