Local tumescent anaesthesia with ambulatory phlebectomy according to Muller principal

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We want to demonstrate or exclude through this study that the administration of a dilute anesthetic solution, using local tumescent anesthesia technique, will lead to a significant decrease in per-and postoperative pain in patients undergoing...

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

Summary

ID

NL-OMON36828

Source
ToetsingOnline

Brief title
LTAFM

Condition

- Venous varices

Synonym
Varices, varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium medisch centrum zal de medicatie vergoeden

Intervention

Keyword: Local tumescent anaesthesia, phlebectomy

Outcome measures

Primary outcome

Pain scores according to standardized VAS score form, scale of 0 to 10. Also returning to work, use of pain medication, type and quantity. As a final, there will be a global use should be made of pain score at the time of surgery, with the following type indications; extreme, rather, light, no pain.

Secondary outcome

Secondary outcomes, in both control and intervention patients:

o Patient satisfaction

o Complications (bleeding, infection, paresthesia, deep vein thrombosis)

o Recovery time (days until full work recovery)

o Usage of pain medications, type and amount

o Global pain score, during surgery with the following types: Extreme, some, light, no pain. This will be assessed 30min after the start of the procedure by the surgeon.

Study description

Background summary

This research will relate to patients who will undergo ambulatory flebectomieën. We mean that patients are classified according to the CEAP classificatie4 and therefore can be treated surgically for varices using the Muller technique.
The Muller technique means that, varicose veins through small incisions (about 1-2mm) removed with a flebotoom. At the height of the incisions by means of

local infiltration (tumescent anesthesia) with lidocaine for local anesthesia.
A flebotoom can best be described as a small spatula, with which the varicose veins to be loosened so that the end with the aid of a Oeschhaakje, the varices can be mounted and by the small skin incision are removed. By making use of the millimeter large incisions to a few millimeters, it is not necessary to use these to attach. This treatment will take about 60-90minuten take.

Tumescent (local) anesthesia involves anesthetic subcutaneously by the vascular surgeon who will perform the procedure. This type of anesthesia is within a few minutes (3-5) minutes incorporated and will average 90 minutes work. Tumescent local anesthesia (LTA) is widely used in plastic surgery and dermatology among other at flebectomie1. Local anesthesia in ambulatory phlebectomy procedures regularly used, however this is often accompanied by many per-and postoperative pain. This type of local anesthetic is also used for many years in plastic surgery, including liposuction at. Here, very good results have been achieved, inter alia, with less risk of bleeding and good pain control during and after the procedures. However, the problem remains flebectomieën the per-and postoperative pain that patients experience.
There are several ways to try to reduce this pain, it now appears that by sodium bicarbonate in small concentrations to be added to the pain is significantly reduced. A recent study has confirmed this effectiveness, by a solution of 1% lidocaine diluted in 1.4% sodium bicarbonate varicose vein surgery (Creton et al, 2011) 1. This study thus shows that the buffering of the acid anesthetic improved pain reduction.
Creton et al1 shows a significant pain reduction, both perioperatively and postoperatively by adding sodium bicarbonate 1.4% to the normal anesthetic. Tumescent anesthesia with lidocaine 1% addition of dilute sodium bicarbonate 1.4% in varices surgery can provide a significant decrease in per-and postoperative pijn1. The use of sodium bicarbonate as a mere excipient is 1.4% LTA is much stronger, so that surgery is much easier, and there is no need for intravenous sedatie1. The use of large volumes of dilute local anesthesia in the subcutaneous tissues allows for anesthesia. Adrenaline reduces blood loss and prolongs the duration of the anesthesie2

We want to demonstrate or exclude through this study that the administration of a dilute solution anesthetic with sodium bicarbonate addition, using local tumescent anesthesia technique, will lead to a significant decrease in per-and postoperative pain in patients undergoing ambulatory phlebectomy will undergone Muller.

The only difference with the current protocol in the hospital will consist of the addition of sodium bicarbonate to the standard anesthetic. In short, the buffering of the acid anesthetic, lidocaine, with the aid of sodium bicarbonate the base, it will give less pain in patients who are ambulatory phlebectomy will undergo according to the Muller technique. We will make use of lidocaine 1%, this is like the current protocol already provides for this type of treatment.

The aim of this study is to demonstrate the benefits of reducing pain associated with local infiltration anesthesia for ambulatory phlebectomy. By means of a dilution of 1% Lidocaine anesthetic with epinephrine + 1.4% sodium bicarbonate to solve

The study described above hypothesis and has led to the creation of the following study. Preoperative informed consent will be obtained before patients were randomized into 2 groups, the experimental group and the control group. Assignment to group 1 or 2 will be independently produced and will be stored in a separate file by the investigator.
Randomisation will take place on the basis of a randomization program (http://www.graphpad.com/quickcalcs/randomize2.cfm). This randomization will be performed before the study begins, so that the total population of 100 patients were randomized to be immediately after inclusion and obtained informed consent. Following participation patients will have a number assigned that will lead to the eventual randomization. That is, experimental (A / B) or control (A / B) group. Assignment to group A or B will be independently produced and will be stored in a separate file by the investigator.
Randomisation is done by the preoperative preparation of the solution by the pharmacist. The pharmacist will advance a large amount of sodium bicarbonate and sodium chloride prepared in vials of 16ml. These are then coded into A or B. This encoding is allocated to the patients on the basis of the former randomization. The perioperative nurse / surgeon vials of 16ml mixed with 4 ml lidocaine 1%, as the research requires. In this way we ensure a double blind, since both patient, surgeon and researcher is not aware of any fluid used during the procedure. These fluids have a retention period of 24 months at room temperature after fabrication.

In all patients, using the standardized analog VAS pain score to determine how much pain they have, this will perioperatively and postoperatively on the day, day 1, day 2, 1 and 2 weeks after the surgery to be recorded. It also will look at content and restore functionality. These will be assessed with a questionnaire.
The follow-up will be carried out by the researcher and the vascular surgeons participating in the study. Patients will check out 2 weeks postoperatively, after which they can indicate the degree of satisfaction of the VAS pain score. It will also look at the potential intake of painkillers and whether this has given satisfactory results. Also, time to return to work can be viewed and restore functionality to look.
Patients will also be six weeks after surgery approached about satisfaction. See diagram above for scores.

Study objective

We want to demonstrate or exclude through this study that the administration of a dilute anesthetic solution, using local tumescent anesthesia technique, will lead to a significant decrease in per-and postoperative pain in patients

undergoing ambulatory phlebectomy according to Muller will undergo. The only difference with the current therapy will consist of the addition of sodium bicarbonate to the standard anesthetic. This standard, unlike the current protocol in the hospital prescribed in the treatment of varicose veins. With the idea that this basic solution the acid buffering lidocaine, with less pain as a result. In short, the buffering of the acid anesthetic, lidocaine, with the aid of sodium bicarbonate the base, it will give less pain in patients who are ambulatory phlebectomy will undergo according to the Muller technique. The aim of this study is to demonstrate the benefits of reducing pain associated with local infiltration anesthesia for ambulatory phlebectomy. By means of a dilution of 1% Lidocaine anesthetic with epinephrine + 1.4% sodium bicarbonate to solve

Study design

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Intervention

Experimental: Alkalinised anesthetic solution Drug: Lidocaïne chlorhydrate 1% in Sodium Bicarbonate 1.4% 4 mL mepivacaine chlorhydrate 20 mg/mL with epinephrine 5 mcg/mL diluted with 16 mL sodium bicarbonate 1.4% Other Names: Active Comparator: Non alkalinised anesthetic solution Drug: Lidocaïne chlorhydrate 1% with epinephrine in NS 0.9% 4 mL Lidocaïne chlorhydrate 20 mg/mL with epinephrine 5 mcg/mL diluted with 16 mL sodium chloride 0.9% Other Names:

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
At a pre-set maximum dose on the basis of weight, there will be a dose-dependent toxicity that can not be achieved. In addition, fewer patients will have per- and postoperative pain. The low tax they undergo as a result of completing the questionnaire and the high percentage of patients from previous studies that this intervention would undergo again proves that the risks are minimal, compared to the potentially significant benefits. Normally during these surgery no more then 50-60milliliter anestheticum is used, this shows that the maximum toxical limit is far from reached

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 (Aged > 18Years or older) indication for ambulatory phlebectomy according to Muller principal

Exclusion criteria

* Allergy to amide anesthetics
* Acute diseases
* Chronic kidney or liver disease
* Treatment with drugs that alter pain sensitivity (eg. analgesics)
* Treatment with monoamine oxidase inhibitors or tricyclic antidepressants
* Major psychiatric disorders according to DSM IV-TR diagnostic criteria
* Alcohol abuse

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2013

Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	epinephrine
Generic name:	Adrenaline
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lidocaïne chlorhydrate 2%
Generic name:	Hydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-11-2012
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
EudraCT	EUCTR2012-003132-23-NL

Register	ID
CCMO	NL41354.096.12