ULTRASOUND-GUIDED SAPHENOUS NERVE BLOCK: A DOSE-FINDING STUDY IN HEALTHY VOLUNTEERS

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The general aim of the present study is to identify the minimum local anaesthetic dose (ED95) of mepivacaine in healthy volunteers.

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

Summary

ID

NL-OMON42255

Source
ToetsingOnline

Brief title
DFSaph

Condition

- Other condition

Synonym
nerve blockade, postoperative pain

Health condition

postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dose-finding, Saphenous nerve block

Outcome measures

Primary outcome

The primary objective of the present study is to determine the ED95 of

mepivacaine 2% to elicit saphenous nerve blockade, tested dichotomous (yes/no)

by loss of sensation to pinprick at all of the following locations:

- the skin over the apex of the Patella,

- the skin of the medial aspect of the medial facet of the tibial plateau and

- the skin over the medial ankle.

Secondary outcome

Secondary aims are to evaluate the influence of volume on duration of sensory

blockade, on the extent of potential motor blockade, block onset and block

offset, and maximum spread of sensory block on the skin surface.

Study description

Background summary

Blockade of the saphenous nerve may be well suited to provide postoperative analgesia in knee surgery. Several researchers have described the efficacy of saphenous nerve block to prevent or treat postoperative pain following major knee surgery,2 however, a great variation in the volume of the local anesthetic used for this nerve block is reported, and volumes between 10 and 30 mL of local anesthetic have been described in literature. So far, no clinical trials have investigated the minimum local anesthetic dose (ED95) of mepivacaine for

ultrasound-guided saphenous nerve block.

Study objective

The general aim of the present study is to identify the minimum local anaesthetic dose (ED95) of mepivacaine in healthy volunteers.

Study design

This present study is an observational, double blind (volunteer, assessor) prospective cohort study.

Intervention

Saphenous (mid thigh) nerve block: patients will receive a distal ultrasound-guided saphenous nerve block. The block is performed using an amount of mepivacaine 2% dictated by the Dixon model.

Study burden and risks

Blockade of the purely sensory saphenous nerve is achieved under ultrasound guidance, and consists of a single injection of local anesthetic typically within 2 cm of skin level as described before at the distal thigh. The risk of this intervention can safely be described as very low.

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

Age 18-65 years, ASA physical status I-II (healthy).

Exclusion criteria

allergy against local anesthetics, contraindication for saphenous nerve block (infection at injection site, local pathology), ingestion of any pain medication within the past 24 hours, pregnancy or breastfeeding status.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL51307.018.14