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How much volume of a local anesthetic is necessary to accomplish a nervus saphenous block

Submission date
22/01/2016

Recruitment status
No longer recruiting

Registration date
25/01/2016

Overall study status
Completed

Last Edited
25/01/2016

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When a person has had surgery on their knee or inside of the lower leg (tibia), effective pain relief is very important part of recovery and rehabilitation. Ideally, pain relief would allow a patient to move their leg and be able to stand or walk (mobilise) straight away after an operation, without complications. An emerging form of providing pain relief for these patients is by using a technique called a saphenous nerve block. This involves injecting a local anaesthetic (numbing agent) into the saphenous nerve. It is the longest branch coming off the femoral nerve (the main nerve that supplies the leg) and is a pure sensory nerve, meaning that it is responsible for detecting sensations (such as temperature, touch or pain) and does not affect movement. The nerve block procedure works by "turning off" (blocking) the pain signals coming from the affected area and preventing excess inflammation (swelling). Many nerve block procedures also affect motor nerves (responsible for controlling movement), and so can prevent patients from moving, possibly slowing down their recovery. It is well known that using a large volume of anaesthetic in a nerve block procedure can lead to unwanted spreading to motor nerves (motor blockade). The aim of this study is to find the minimum effective local anesthetic dose to perform a saphenous nerve block in healthy volunteers.

Who can participate?
Healthy adults aged between 18 and 65.

What does the study involve?
All participants receive an ultrasound-guided saphenous nerve block on their left leg. This involves using an ultrasound probe (which uses high-frequency sound waves) to visualize the nerves in the leg, to guide the injection of mepivacaine (local anaesthetic) along the saphenous nerve. The needle which injects the mepivacaine enters the skin at mid-thigh level, and is guided into the correct place using the ultrasound images of the leg, projected onto a screen. The amount of anaesthetic needed to achieve a nerve block in each patient determines how much is given to the next patient (i.e. increasing the dose by 1ml each time). Thirty minutes after the

block, all participants have the area of skin that is controlled by the saphenous nerve pricked with a pin and are asked whether they can feel it so that the most effective dose can be worked out.

What are the possible benefits and risks of participating?
There are no direct benefits for participants taking part in the study, although they do receive financial compensation for travel costs. There is a very small risk of infection, bleeding or nerve damage, however this is unlikely.

Where is the study run from?
Academic Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
November 2014 to November 2015

Who is funding the study?
Academic Medical Center (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2014-004672-38

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20141125 V2

Study information

Scientific Title
Minimum local anaesthetic volumes for saphenous nerve block: A dose-finding study

Study objectives
The aim of this study is to characterize the minimum volume of local anesthetic volume effective saphenous nerve block in volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Academic Medical Centre, 05/01/2015, ref: 2014_348

Study design
Non-randomized single-centre single group dose esclation study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Saphenous nerve block

Interventions
Patients will receive a distal ultrasound-guided saphenous nerve block. Briefly, the ultrasound probe will be used to locate the femoral artery over the medial aspect of the thigh. The artery will be followed distally until it moves posteriorly through the adductor hiatus. Block will be performed 2 cm to this location. At this point, the saphenous nerve is in immediate proximity, medial to the artery. The block is performed using an amount of mepivacaine 2% dictated by the Dixon model.

Each patient’s response to the nerve block determines the volume of mepivacaine for the next patient. When successful saphenous nerve block is achieved, the volume for the next patient will

be decreased with 1ml mepivacaine. Conversely, when no block can be detected, the volume for the next study patient will be increased with 1 ml mepivacaine. As described by Dixon, the study is finished after three oscillations (up/down) around a given volume. From these data, ED95 and ED50 can be calculated.

After the nerve block, an assessment of block onset will be performed at the apex patellae and, after 20 minutes, assessment of the main study parameter, block yes/no. After this, motor weakness is determined, and the sensory area anesthetized is mapped on the skin surface of each volunteer. Finally, block duration is determined by measuring every 15 minutes until sensory block disappears. The total duration of the intervention takes 4 hours maximum for a complete block offset. When the block wears of the volunteer completed the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Effective volume to produce complete neural blockade is determined using a pinprick in the sensory area of the saphenous nerve to provoke a dichotomous yes/no answer, 30 minutes after block.

Secondary outcome measures
1. Influence of the volume on duration of sensory blockade is measured using pinpricks at the apex of the patella, medial aspect of the medial facet of the tibial plateau and the skin over the medial ankle at 2, 4, 6, 8, 10, 15, 20, 25, and 30 minutes, and then every 15 minutes until block resolution
2. Extent of potential motor blockade is measured using the MRC-scale 20 minutes after block onset
3. The maximum spread of sensory block on the skin surface is measured using pinpricks to establish the edge of the anaesthetised area 20 minutes after block onset

Overall study start date
01/11/2014

Completion date
01/11/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. ASA physical status I-II (healthy)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not possible to determine before start of the study, but expected is no more than 25 volunteers

Key exclusion criteria
1. Allergy against local anesthetics
2. Contraindication for saphenous nerve block (infection at injection site, local pathology)
3. Ingestion of any pain medication within the past 24 hours
4. Pregnancy or breastfeeding

Date of first enrolment
12/02/2015

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Meibergdreef 9
Amsterdam
Netherlands
1105AZ

Sponsor information

Organisation
Academisch Medisch Centrum (Academic Medical Center)

Sponsor details
Meibergdreef 9
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academisch Medisch Centrum (Academic Medical Center)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request