Effect of local anesthetic dose versus volume on block duration of single shot ultrasound-guided axillary brachial plexus block with mepivacaine.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37783

Source
ToetsingOnline

Brief title
VolCon

Condition

- Bone and joint therapeutic procedures

Synonym
forearm, wrist or hand orthopedic surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Onderzoek wordt intern gefinancierd

Intervention

Keyword: Dose, Duration, Mepivacaine, Volume

Outcome measures

Primary outcome

Duration of sensory ABPB (overall and individual nerves).

Secondary outcome

Duration of motor block (overall and individual nerves)

Onset of sensory and motor block (overall and individual nerves),

Number of rescue blocks

Time to first request for postoperative analgesia

Satisfaction (NRS 0-10) with the anesthetic technique

Study description

Background summary

Peripheral nerve block (PNB) as an anesthetic technique plays an important role in modern regional anesthesia. Duration of PNB depends on several factors such as the choice of local anesthetic (LA), the site of injection and the dose of LA. The dose of local anesthetic administered when performing peripheral nerve block is determined by volume and concentration; in what way these parameters affect duration is controversial. Using ultrasound guidance, LA spread around the nerves can be assessed with the possibility of repositioning the needle in case of maldistribution. Recent publications illustrate that the volume of LA can be significantly reduced when particular regional anesthetic techniques are performed with ultrasound guidance.
In a recent study, we compared the duration of sensory and motor block with 15 and 40 millilitres mepivacaine 1.5% for axillary brachial plexus block using ultrasound guidance. Dose reduction from 40 mL to 15 mL (62.5%) shortened the overall duration of sensory and motor block by approximately 17-19% in our study. It reduced sensory and motor block duration of individual nerves with 18-40% and decreased the time to first request of postoperative analgesia with

approximately 30%. The difference in block duration in our study may be the effect of either reducing the volume from 40 to 15 mL, or of reducing the dose from 600 to 225 mg. In previous research, duration of analgesia reported by Serradell et al. was 231 ± 45 min in their group receiving axillary block with 200 mg mepivacaine in 20 mL. Interestingly, the TTFR in our group 40 mL (600 mg mepivacaine) was similar (235 ± 59 min), whereas the TTFR in our group 15 mL (225 mg mepivacaine) was considerably shorter. Although differences in methodology preclude making direct comparisons, these observations may indicate that the reduction in block duration seen in our study is caused by the reduction in volume from 40 mL to 15 mL rather than the reduction in dose from 600 mg to 225 mg. However, further study is required to substantiate this. Therefore, the purpose of the current study is to determine the effect of mepivacaine dose and volume on the duration of sensory axillary brachial plexus block (overall and individual nerves).

Study objective

Primary objective: to determine the effect of mepivacaine dose and volume on the duration of sensory axillary brachial plexus block (overall and individual nerves).
Our hypothesis (H0) is that there is no difference (less than 60 min) in duration of ABPB using the different amounts of local anesthetic (volume and dose) under ultrasound guidance.
Secondary objectives: effect of dose and volume on; duration of motor block (overall and individual nerves); onset of sensory and motor block (overall and individual nerves); number of rescue blocks; Time To First Request of postoperative analgesia (TTFR); and satisfaction (NRS 0-10) with anesthetic technique.

Study design

The design of this study is parallel, prospective, randomized and blind (for patient and data collector). The study will be conducted at the Sint Maartenskliniek, Nijmegen, The Netherlands approximately between 1-3-2012 and 01-03-2014. Patient inclusion is expected between april 2012 and april 2013, but may be prolonged if the sample size has not yet been reached.

Intervention

Using a computer-generated sequence of random numbers and a sealed envelope technique, patients will be randomly allocated to receive single shot axillary brachial plexus block with either 30 mL mepivcaine 1.0% (300 mg), 30 mL mepivacaine 1,5% (450 mg) or 20 mL mepivacaine 1,5% (300 mg). This study is blinded for patient and data collector. The attending anesthesiologist will be aware of treatment allocation.

Axillary block will be performed by experienced anesthesiologists with a combination of nerve stimulation and ultrasound. The musculocutaneus, median, ulnar and radial nerve will be identified separately. Each nerve will be blocked by either 7-8 mL (30 mL groups) or 5 mL (20 mL group). Time is designated t = 0 upon conclusion of the axillary brachial plexus block. Surgery will be performed under regional anesthesia alone, or supplemented with sedation, or supplemented with general anesthesia. All patients will be treated according to standard hospital protocol.

Baseline characteristics of participating patients will be recorded (i.e. age, length and weight). Also, the name of the anesthesiologist performing the block and the ease of block performance will be noted.
In the first 30 minutes after injection of local anesthetic solution, a blinded observer will assess the onset of sensory and motor block every 5 minutes until ABPB is complete. The sensory block of the musculocutaneus, median, ulnar and radial nerves will be assessed by pinprick at specific sites. In addition, sensory block of the medial antebrachial cutaneus nerve will be tested. Sensory block will be scored on a three-point scale as 0 = absent, 1 = partial and 2 = complete. Motor function of the musculocutaneous, median, radial, and ulnar nerve will also be assessed on a three-point scale as 0 = no motor block, 1 = partial and 2 = complete. A complete sensory block is defined as a total score of 10, complete motor block is defined as a total score of 8. If necessary, supplemental blocks will be placed if sensory block is incomplete at 30 min. The type, side and duration of surgery will be recorded. Upon arrival at the recovery, offset of sensory and motor block will be assessed every 15 minutes until full recovery in the same manner as preoperatively. Full sensory and motor recovery are defined as the time that a total score of 0 is first obtained. In addition, the time to first request for analgesia as well as patient satisfaction with the anesthetic technique will be recorded.

Study burden and risks

Block duration will be tested every 15 minutes postoperatively in patients who participate in this study until the block has resolved completely. We think this minor burden does not outweigh the information we can obtain to optimally treat future patients. There are no specific benefits for the patient to participate in this study, nor are there specific risks.
This study is not group related.

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 of 18 years or older
- ASA physical status classification I - III
- Patients undergoing single shot axillary brachial plexus block for hand, wrist, or forearm orthopedic surgery
- Written informed consent

Exclusion criteria

- Contra-indications for regional anesthesia
- Known hypersensitivity to amide-type local anesthetics
- Known history of peripheral neuropathy
- Any other reason which in the opinion of the investigator makes the patient unsuitable for participation in the study

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):	11-10-2012
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	mepivacaine
Generic name:	mepivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-05-2012
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Approved WMO Date:	14-06-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen

	(Wijchen)
Approved WMO Date:	14-06-2012
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	25-06-2012
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26805
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-001704-38-NL
CCMO	NL40000.072.12
OMON	NL-OMON26805

Study results

Date completed:	18-06-2014
Actual enrolment:	51

Summary results
Trial is onging in other countries