The effect of local anesthetic volume on the duration of single shot axillary brachial plexus block.

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

Summary

ID

NL-OMON34121

Source
ToetsingOnline

Brief title
AXUS

Condition

- Bone and joint therapeutic procedures

Synonym
hand, wrist or forearm orthopaedic surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: het onderzoek wordt intern gefinancierd

Intervention

Keyword: axillary brachial plexus block, duration, local anesthetic volume, ultrasound guidance

Outcome measures

Primary outcome

Duration of sensory AXB; time to (slight feeling and) full recovery

Duration of motor AXB; time to (slight movement and) full recovery

Secondary outcome

Proportion of patients with complete sensory and motor block 30 min after

injection

Efficacy of AXB

Time to first demand for analgesic medication

Study description

Background summary

Peripheral nerve block (PNB) as an anesthetic technique plays an important role in modern regional anesthesia. The most important prerequisites for the use of peripheral regional anesthesia in the daily clinical practice are success rate and safety. Both issues are closely related to the administered volumes of local anesthetics.
Ultrasound guidance is rapidly gaining popularity among anesthesiologists for the placement of peripheral nerve blocks because it offers several potential advantages compared with conventional methods. Nerves and other anatomical structures such as vessels, muscles, bones, fascias and tendons, can be visualized directly. Also, local anesthetic (LA) spread around the nerves can be assessed with the possibility of repositioning the needle in cases of maldistribution. Ultrasound guidance shortens the block performance time, reduces the number of needle insertions and shortens the block onset time. It probably even reduces complication rates, because the needle can be visualized at all times and intraneural and intravascular injection can be avoided. Recent publications illustrate that the volume of local anesthetic (LA) can be significantly reduced when particular regional anesthetic techniques are

performed with ultrasound guidance.

The axillary approach to block the brachial plexus is widely used to provide anesthesia for surgery of the forearm, wrist and hand. To block the brachial plexus in the axilla, deposition of local anesthetic is required adjacent to the nerves (the median, radial, ulnar, musculocutaneous and medial antebrachial cutaneous nerves). The procedure is relatively safe and, if dose limits are observed, complications are uncommon.
Before the introduction of nerve stimulation and/or ultrasound guidance, blind injection of the local anesthetic around the axillary artery (infiltration technique) was the predominant method used to block the axillary brachial plexus. Failures or incomplete blocks were thought to be caused by imprecise needle placement or septation of the brachial plexus sheath, leading to malposition of the local anesthetic. Recent research is largely concerned with identifying volumes of local anesthetic and techniques to *fill* the axillary brachial plexus sheath to *capacity*. Furthermore, investigators attempt to define the relationship between dose, volume, and concentration of the local anesthetic and reliability, quality, and duration of the blockade.

To date, there are no data considering duration of peripheral nerve blocks in low volumes using ultrasound guidance. There may be a linear relationship, but it is also conceivable that with higher doses, a large part of the local anesthetic will be absorbed and redistributed without contributing to nerve blockade.

Study objective

The purpose of the present study is to compare the duration of sensory and motor block with 15 and 40 millilitres mepivacaine 1.5% for axillary brachial plexus block using ultrasound guidance. Our hypothesis (H0) is that there is no difference (less than 60 min) in duration of AXB using the different amounts of local anesthetic under ultrasound guidance.

Study design

The design of this study is parallel, prospective, randomized and single blind. Thirty patients scheduled for single shot axillary brachial plexus block for hand, wrist or forearm orthopaedic surgery will be studied.

Study burden and risks

Currently, many peripheral nerve blocks are perfomed under ultrasound guidance. This allows for significant reduction of the volume of local anesthetic (LA), wich diminishes the risk for neural toxicity. It is important however, to maintain sufficient block duration for postoperative pain control. Block duration will be tested every 30 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.

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, 18 years or older
- Body weight over 50 kg
- ASA classification I - III
- Patients undergoing single shot axillary brachial plexus block for hand, wrist or forearm orthopaedic surgery
- Written informed consent

Exclusion criteria

- Contra-indications for regional anesthesia
- Known hypersensitivity to amide-type local anesthetics
- Known history of peripheral neuropathy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2010
Application type:	First submission
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: 23905
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32432.072.10
OMON	NL-OMON23905