Werkingsduur van het axillaire brachiale plexus blok voor pols-, hand- en onderarmchirurgie met kleine hoeveelheden lokaal anestheticum onder echogeleiding.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23905

Bron
Nationaal Trial Register

Verkorte titel
AXUS

Aandoening

single shot axillary brachial plexus block for hand, wrist or forearm orthopaedic surgery

Ondersteuning

Primaire sponsor: Sint Maartenskliniek, Nijmegen
Overige ondersteuning: Sint Maartenskliniek, Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Duration of sensory AXB: Time to (slight feeling and) full recovery;
2. Duration of motor AXB: Time to (slight movement and) full recovery.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. T = 0 upon conclusion of the axillary nerve block;

2. Until T = 30, the onset of sensory and motor block is assesed every 5 minutes until axillary block is complete;

3. T = 0PO upon arrival at the post anesthesia care unit.

Offset of sensory and motor block will be assessed every 15 minutes until full recovery.

Onderzoeksproduct en/of interventie

Experienced anesthesiologists will place all blocks with either 15 or 40 mL of mepivacaine 1.5%, according to a computer-generated randomization list.

Axillary block will be performed 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 10 mL (40 mL group) or 3-4 mL (15 mL group).

Time is designated T = 0 upon conclusion of the axillary nerve block. Surgery will be performed under regional anesthesia, supplemented if necessary with sedation using propofol, remifentanil and a laryngeal mask airway.
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 axillary block 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 and duration of surgery, efficacy of the AXB and time to first request for postoperative pain treatment will be recorded. The efficacy of the block will be assessed as successful (no supplemental blocks and no additional intraoperative medication), partial (intraoperative additional medication) or unsuccessful (general anesthesia).

Upon arrival at the post-anesthetic care unit, 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 demand for analgesia will be recorded.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients of 18 years of age or older;

2. Body weight over 50 kg;

3. ASA classification I – III;

4. Patients undergoing single shot axillary brachial plexus block for hand, wrist or forearm orthopaedic surgery;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contra-indications for regional anesthesia;

2. Known hypersensitivity to amide-type local anesthetics;

3. Known history of peripheral neuropathy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-06-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34121
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2245
NTR-old	NTR2371
CCMO	NL32432.072.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34121

Resultaten

Samenvatting resultaten
N/A