Effect van dosis versus volume van mepivacaine op de werkingsduur van echo geleid axillair plexus blok.

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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...

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

Samenvatting

ID

NL-OMON26805

Bron
NTR

Verkorte titel
VolCon

Aandoening

axillary plexus blok; mepivacaine; éénarmsblok; blokverdoving; regional anesthesia; blokverdoving

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Duration of sensory ABPB (overall and individual nerves).

Toelichting onderzoek

Achtergrond van het onderzoek

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.6 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.7 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).

Doel van het onderzoek

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); Time To First Request of postoperative analgesia (TTFR); and satisfaction (NRS 0-10) with anesthetic technique.

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

Intravenous access and routine monitoring will be established in all patients. Experienced anesthesiologists will place all blocks with 30 mL mepivacaine 1.0% (300 mg), 30 mL mepivacaine 1,5% (450 mg) or 20 mL mepivacaine 1,5% (300 mg), 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 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. In case of inadequate anesthesia patients will be converted to general anesthesia.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients ≥ 18 years;

2. ASA physical status classification I – III;

3. Patients undergoing single shot ABPB for hand, wrist, or forearm orthopedic surgery;

4. 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;

4. Any other reason which in the opinion of the investigator makes the patient unsuitable for participation in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	03-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37783

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3502
NTR-old	NTR3648
CCMO	NL40000.072.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37783

Resultaten

Samenvatting resultaten
Effect of local anesthetic concentration, dose and volume on the duration of single-injection ultrasound-guided axillary brachial plexus block with mepivacaine: a randomized controlled trial