Het effect van adrenaline toegevoegd aan het verdovingsmiddel, op de werkingsduur van de voetverdoving.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23190

Source
NTR

Brief title
TTFR

Health condition

Patients scheduled for continuous popliteal sciatic nerve block for talocrural arthrodesis; subtalar fusion or Lisfranc arthrodesis at the Sint Maartenskliniek

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Sint Maartenskliniek Nijmegen

Intervention

Outcome measures

Primary outcome

Duration of postoperative analgesia depicted in Time To First Request: time between t = 0 and time of first request for postoperative analgesia (PCA ropivacaine 0.2% through popliteal

catheter).

Secondary outcome

1. Onset of sensory and motor block;

2. Numeric Rating pain Scores (NRS 0-10) at rest and during movement directly postoperative, at t = 24h and if necessary at t = 48h;

3. Satisfaction (NRS 0-10) with anesthetic technique.

Study description

Background summary

Duration of peripheral nerve block depends on several factors such as the choice of local anesthetic (LA), the site of injection and the presence of adjuncts such as clonidine or epinephrine. Epinephrine may be added to large doses of local anesthetics (LA) with the objective to reduce the maximum plasma concentration or to act as a marker for intravascular injection. The rationale for adding epinephrine to reduce the maximum plasma concentration is local vasoconstriction at the site of injection, thereby slowing absorption. This also has an effect on the duration of analgesia of the LA, because the LA remains available around the nerve for a longer period of time.

Ropivacaine has intrinsic vasoconstrictive properties. A study by Cederholm et al. shows no additional prolongation of sensory or motor block after epidural anesthesia with ropivacaine with epinephrine compared to ropivacaine alone. For perivascular subclavian block, Hickey et al. found no effect on pharmacokinetics (Cmax, tmax or AUC) after the addition of epinephrine to ropivacaine. Weber et al. show that the addition of epinephrine to ropivacaine for femoral nerve block has no effect on duration of analgesia, expressed in time to first request for postoperative analgesia.
On the other hand, some studies do find a decrease in Cmax and an increase in tmax as result of adding epinephrine to ropivcaine for epidural, caudal or regional (thoracic paravertebral block) anesthesia.

In a recent pilot study (NTR1973) we found an indication of prolonged TTFR after the addition of epinephrine to ropivacaine for combined sciatic/femoral nerve block for anterior cruciate ligament reconstruction. This rises the question whether the addition of epinephrine to ropivacaine could prolong postoperative analgesia after peripheral nerve blocks.

Study objective

The purpose of the present study is to compare duration of postoperative analgesia depicted in Time To First Request (TTFR) with 30 milliliters ropivacaine 0.75% with and without

epinephrine for popliteal sciatic nerve block using ultrasound guidance.

Study design

T=0: Upon conclusion of popliteal sciatic nerve block;

Until T=45 min: The onset of sensory and motor block is assesed every 5 minutes until sciatic nerve block is complete;

T=24h: The PCA pump will be checked and TTFR will be noted. This is the end of the study. In case no request for postoperative analgesia has been made at t=24h, the patient will be followed up again at t=48h.

Intervention

Experienced anesthesiologists will place all blocks with ropivacaine 0.75% either with or without epinephrine 5 ìg/mL (1:200.000), according to a computer-generated randomization list.
Continuous popliteal sciatic nerve block will be performed with a combination of nerve stimulation and ultrasound using a posterior approach. The tibial and peroneal nerve will be identified at the level of bifurcation of the sciatic nerve by either plantar (tibial nerve) or dorsal (peroneal nerve) flexion of the foot. Thirty milliliters ropivacaine 0.75% with or without epinephrine 5 ìg/mL will be injected in fractionated doses. Time is designated t = 0 upon conclusion of the popliteal sciatic nerve block. A perineural catheter will be inserted trough the needle after injection of the loading dose. An additional single shot femoral or saphenus nerve block will be placed after the popliteal block with 20 mL mepivacaine 1.5% to facilitate surgery (tourniquet). Surgery will be performed under regional anesthesia alone, or supplemented with sedation, or supplemented with general anesthesia. After surgery, upon arrival at the recovery room, a PCA-pump (GemStar®, Hospira Inc. Lake Forest, Illinois, USA) will be connected to the popliteal catheter set up to deliver incremental doses of 10 mL ropivacaine 0.2%, with a lock-out of 15 minutes, no background infusion and a maximum of 30 mL per 4 hours. Patients will be instructed to use the PCA device to maintain postoperative pain scores at or below NRS 3.
In the first 45 minutes after injection of local anesthetic solution, a blinded observer will assess the onset of sensory and motor block every 5 minutes until popliteal sciatic nerve block is complete. The sensory block of the tibial and peroneal nerves will be assessed by pinprick at specific sites. Sensory block will be scored on a three-point scale as 0 = absent, 1 = partial and 2 = complete. Motor function of the tibial and peroneal nerve will also be assessed on a three-point scale as 0 = no motor block, 1 = partial and 2 = complete motor block. Complete sensory and motor block is defined as a total score of 4 and 4. The type, side and duration of surgery will be recorded. At t = 24h the ropivacaine consumption will be checked in the PCA pump. Time of first PCA bolus is noted. In case no request has been made, sensory and motor block will be tested in the same manner as preoperative and ropivacaine consumption will be additionally checked at t = 48h. Also, NRS scores at rest and during movement will be recorded as well as patient satisfaction with the anesthetic technique.

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Eligibility criteria

Inclusion criteria

1. Patients of 18 years or older;

2. ASA physical status classification I – III;

3. Patients undergoing continuous popliteal sciatic nerve block for foot arthrodesis surgery;

4. Written informed consent.

Exclusion criteria

1. Contra-indications for regional anesthesia;

2. Known hypersensitivity to amide-type local anesthetics;

3. Known history of peripheral neuropathy;

4. Inability to understand numerical pain scores;

5. Inability to operate a Patient-controlled Analgesia (PCA) device.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	05-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3186
NTR-old	NTR3330
CCMO	NL39628.072.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A