Study to describe the processing of ropivacaine in the body when injected in the knee for pain treatment in total knee arthroplasty.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24359

Source
Nationaal Trial Register

Brief title
Llakin II

Health condition

Total Knee Arthroplasty
Ropivacaine
tourniquet
Pharmacokinetic profile

Totale knieprothese
ropivacaine
bloedleegteband
farmacokinetisch profiel

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Sint Maartenskliniek Nijmegen, dept. of Anesthesiology

Intervention

Outcome measures

Primary outcome

- Mean total and unbound maximum serum concentration of ropivacaine (Cmax and Cumax)

- Mean time to total and unbound maximum serum concentration of ropivacaine (Tmax an Tumax)

Secondary outcome

not applicable

Study description

Background summary

Local infiltration analgesia (LIA) with ropivacaine for total knee arthroplasty (TKA) is increasingly used. Despite the high doses of ropivacaine, LIA is considered safe, and this perception is sustained by pharmacokinetic data demonstrating that maximum concentrations of ropivacaine stay well below the toxic threshold in plasma. These pharmacokinetic studies all involve TKA procedures with the use of a tourniquet. Recently, performing TKA without the use of a tourniquet is gaining popularity, but no pharmacokinetic data exist when LIA is administered for TKA without the use of a tourniquet. The purpose of this study was to describe the pharmacokinetic profile of a single-shot ropivacaine (200 mL 0.2%) and 0.75 mg epinephrine (1000 µg/mL) when used for LIA in patients for TKA without a tourniquet. In this prospective cohort study, 20 patients treated with LIA for TKA without a tourniquet are studied. Plasma samples are taken at 20, 40, 60, 90, 120, 240, 360, 480, 600, 720, and 1440 minutes after local anesthetic infiltration, in which total and unbound ropivacaine concentrations are determined.

Study objective

not applicable

Study design

baseline, 20, 40, 60, 90, 120, 240 ,360, 480, 600, 720 and 1440 minutes after ropivacaine infiltration

Intervention

bloodsamples 12 times 5-10 ml

Contacts

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Eligibility criteria

Inclusion criteria

- age 50-80 years

- ASA physical health classification I ¨C II

- Body Mass Index (BMI) < 40

- Patient planned for a primary unilateral posterior-stabilized tri-compartmental cemented total knee replacement (Genesis II - PS) under unilateral spinal anesthesia with 2 mL hyperbaric bupivacaine 0.5%

- Scheduled for fast-track protocol TKA

- Hemoglobin (Hb) concentration ¡Ý 7.5 mMol/L

- Written informed consent

Exclusion criteria

- Placement of a surgical drain

- Contra-indications for spinal anesthesia

- Known hypersensitivity to amide-type local anesthetics

- Hepatic or renal insufficiency

- Use of fluvoxamine, ciprofloxacin, ketoconazole, erythromycin, clarithromycin, itraconazole, or rifampicin because of their effect on ropivacaine clearance.

- Any reason to perform surgery with the use of a tourniquet

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2017
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 16-01-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45473
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6159
NTR-old	NTR6306
CCMO	NL60548.048.17
OMON	NL-OMON45473

Study results

Summary results
https://rapm.bmj.com/content/43/7/699.long