Comparison of femoral nerve block with posterior capsule infiltration versus anterior and posterior capsule infiltration after total knee replacement

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22055

Source
Nationaal Trial Register

Brief title
LiFeAnKeR

Health condition

Total knee arthroplasty femoral nerve block Local infiltration analgesia

Sponsors and support

Primary sponsor: S. van Kralingen
M. Vogel
OLVG
Amsterdam
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

-Opioid consumption measured by mg of morphine i.v. used daily (every morning at am by painconsulent and/or researcher)

-Mobilization measured by Modified Iowa Levels of Assistance Scale (MILAS)

Secondary outcome

-NRS pain score in rest from the day of surgery until day 3 post surgery

-NRS pain score in flexion exercise from the day of surgery until day 3 post surgery

-NRS pain score postoperatively when walking

-range of motion with flexion and extension during 3 postoperative days

-length of stay in hospital

-side-effects

Study description

Background summary

This prospective randomized controlled trial compares the SFNB group with the LiA group. The SFNB group gets a femoral nerve block with ropivacaine 0.375% and 75 microgram clonidine, and furthermore recieves 50 cc ropivacaine 0.2% with epinephrine 1:100.000 in the posterior part of the capsule. The LIA group recieves local infiltration with 50 cc ropivacaine 0.2% in the anterior capsule and 50 cc ropivacaine 0.2% in the posterior capsule. And the third injection in the subcutis with 50 cc ropivacaine 0.2% without epinephrine to prevent tissue necrosis. Patients meeting the inclusion criteria will receive information about the study and informed consent letters at the anesthesiology outpatients department. The eligible patients receive a call a week after visiting the outpatients department to obtain permission. Informed consent documents will be signed before surgery by the patient and the investigator/anesthesiologist. Patients will be randomized just before the surgery to the SFNB or LiA group.

All patients will receive the same pain medicaticn cperatively: acetominophen 1000 mg Q?D and naproxen BID and a single dose of intravenous metamizol 1000 mg (dipyrone). Moreover all patients receive a patient controlled analgesia pump with morfine. Every morning at 10.00 am the painconsulent and/or the researcher will note how much morphine is consumed. At

the post-anesthesia care unit (PACU) the patients were instructed that no pain and worst possible pain equals to 0 and 10 respectively, on the visual analog scale (VAS). This VAS score is measured at the FACU until day 3 after surgery, and is noted by the patient in their patient journal during rest, flexion exercises and during walking. Side effects like nausea, vomiting, drowsiness, pruritus, paresthesia (day 1 tc 3) and obstipation (at discharge) are registered by the patient in their patient journal as well as by the clinician in the medical file in EPIC.

A total of 90 patients will be included by interviewing them at the time of intake and asking informed consent. Fewer calculations showed that 80 patients are needed to show a difference in opioid consumption

Study objective

This prospective randomized controiied trial designed to compare the quality of analgesia offered by SFNB and LiA and their effects cn morphine consumption, mobilization and pain control postoperatively. Our first hypothesis concerning opioid use is a significantly reduced opioid use in the SFNB group. Seccndiy, we hypothesize that with respect to the mobilization there is no significant difference between SFNB en LIA group

Intervention

Patients in the SFNB group will get a femoral nerve block with ropivacaine 0,375% and 75 microgram clonidine, and furthermore will recieve 50cc ropivacaine 0,2% with epinephrine 1:100.000 in the posterior part of the capsule. The LiA group will receive 3 local infiltrations: 50cc ropivacaine 0,2% in the anterior capsule and 50cc ropivacaine 0,2% in the posterior capsule, and the third injection in the subcutis with 50cc ropivacaine 0,2% without epinephrine to prevent tissue necrosis. Ropivacaine is a local anestheticum which is favorable considering its low cardiovascuiar and neurologic toxicity comparing tc bupivacaine. Moreover it has less motor blokkade compared to bupivacaine.

Contacts

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Eligibility criteria

Inclusion criteria

Patients 18 years and older who are scheduled for a TKA with spinal anesthesia.

-age above 18 years

-mentally competent

-eligible for TKA

Exclusion criteria

-contra indication for spinal anesthesia(severe aortic stenosis, severely compromised cardiac function

-infection at interspace voor spinal injection

-allergy to used medication

-repeat TKP

-all previous surgeries concerning arthrotomy

-participation in other research protocol

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42184
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5736
NTR-old	NTR5881
CCMO	NL51548.100.15
OMON	NL-OMON42184

Study results