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

Published: 31-03-2015
Last updated: 19-03-2025

This prospective randomized controlled trial designed to compare the quality of analgesia offered by SFNB and LIA and their effects on morphine consumption, mobilization and pain control postoperatively. Our first hypothesis concerning opioid use is...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Bone and joint therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42184

**Source**
ToetsingOnline

**Brief title**
LiFeAnKeR

### Condition

- Bone and joint therapeutic procedures

**Synonym**
mobility, Pain

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Lucas Andreas Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W,0

## Intervention

**Keyword:** femoral nerve block, Local infiltration analgesia, Total knee arthroplasty

## Outcome measures

### Primary outcome

-Opioid consumption measured by mg of morphine i.v. used daily (every morning

at 10.00 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

Total knee arthroplasty (TKA) is a surgical procedure to replace the knee joint. In the Netherlands over 20.000 TKAs were effectuated in 2010. The most common indication for a TKA is arthrosis but other indications include posttraumatic disorders, osteonecrosis, malignancy, disabling pain or severe movement restriction.(1)
Pain after TKA is usually severe, difficult to manage, and insufficient pain relief may delay recovery. Postoperative pain management after TKA is often multimodal and includes oral analgetics, intravenous (i.v.) opioids,

peripheral nerve blocks or epidural analgesia. These treatments are associated with side effects, such as nausea, sedation, hypotension, partial motor block and urinary retention. Local infiltration analgesia with ropivacaine is an alternative treatment with good functional recovery.(2,3)
Femoral nerve blocks(FNB) are presently the gold standard for an effective analgesia approach in TKA.(4,5) FNB should be supplemented with oral opioids. Another option for additional therapy is a posterior capsule infiltration. (6)
Recent studies on application of local anesthetics into the knee have shown that this approach has several advantages compared to other regional or purely systemic approaches.
In a blinded study (Bianconi et al. 2003)2, 37 patients were randomized to receive intraoperative infiltration with ropivacaine or placebo. Intensity of postoperative pain, consumption of rescue analgesics, and length of hospital stay were significantly reduced in the group that received ropivacaine. Open studies have shown similar results. (Rasmussen et al 2004(6), Isaac et al. 2005(7)) Another study compared local infiltration analgesia with a continuous femoral nerve block (Toftdahl et al. 2007)3 Pain scores during physiotherapy and postoperative were significantly better in the local infiltration analgesia group.
A preoperative single shot femoral nerve block(SFNB) is the standard care for analgesia after TKA in the St. Lucas Andreas Hospital and many other hospitals. Although a SNFB gives a satisfied analgesia, the mobilization can be limited by (partial) motor block. Hence, the present study aims to compare two treatments for TKA analgesia: a new treatment with anterior- and posterior capsule infiltration (LIA) and the standard treatment including a single shot femoral nerve block (SFNB) with posterior capsule infiltration. Postoperative mobilization and pain will be measured every day. Moreover, the quality of analgesia will be assessed by consumption of opioid and with VAS score for pain. Secondary outcome measures will be adverse effects of oral and/or i.v. analgesics, length of stay and satisfaction.
REFERENCES
1. De Waal MC, Gaasbeek RDA, Koëter S, et al. Richtlijn totale knieprothese(concept). Nederlandse Orthopaedische Vereniging 2014.
2. Bianconi M, Ferraro L, Traina G C, Zanoli G, Antonelli T, Guberti A, Ricci R, Massari L, Pharmacokinetics and efficacy of ropivacaine continuous wound instillation after joint replacement surgery. Br J Anaesth 2003; 91(6): 830-5
3. Toftdahl K, et al. Comparison of peri- and intraarticular analgesia with femoral nerve
block after total knee arthroplasty. Acta Orthopaedica 2007; 78(2): 172-9.
4. Chan EY, Fransen M, Parker DA, Assam PN, Chua N. Femoral nerve blocks for acute postoperative pain after knee replacement surgery (Review). The Cochrane Library 2014, Issue 5.
5. Bauer MCR, Pogatzki EM, Zahn PK. Regional analgesia techniques for total knee replacement. Curr Opin Anesthesiol 2014, 27:501-506
6. Rasmussen S, Kramhoft M U, Sperling K P, Pedersen J H. Increased flexion and reduced hospital stay with continous intraarticular morphine and ropivacaine after primary total knee replacement: open intervention study of efficacy and

safety in 154 patients. Acta Orthop Scand 2004; 75 (5): 606-9
7. Isaac D, Falode T, Liu P, I*Anson H, Dillow K, Gill P. Accelerated rehabilitation after total knee replacement. Knee 2005; 12 (5); 346-50.

## Study objective

This prospective randomized controlled trial designed to compare the quality of analgesia offered by SFNB and LIA and their effects on morphine consumption, mobilization and pain control postoperatively. Our first hypothesis concerning opioid use is a significantly reduced opioid use in the SFNB group. Secondly, we hypothesize that with respect to the mobilization there is no significant difference between SFNB en LIA group. The outcome of this study may lead to a future modification of the protocol in pain relief for TKA in the St. Lucas Andreas Hospital.

## Study design

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 (see flowchart).
All patients will receive the same pain medication post operatively: acetominophen 1000 mg QID 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 equal to 0 and 10, respectively, on the visual analog scale (VAS). This VAS score is measured at the PACU 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 to 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. Power calculations showed that 80 patients

are needed to show a difference in opioid consumption.

**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 cardiovascular and neurologic toxicity comparing to bupivacaine. Moreover it has less motor blokkade compared to bupivacaine.

**Study burden and risks**

Contribution of patients will take approximately 1 hour of their time for filling in the patient diary. Patients will receive similar treatment as patients who are not included in the study.

# Contacts

**Public**
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
Amsterdam 1061 AE
NL
**Scientific**
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
Amsterdam 1061 AE
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## 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;- informed consent

## Exclusion criteria

-contra indication for spinal anesthesia (severe aortic stenosis, severely compromised cardiac function);- infection at interspace of spinal injection;- allergy to used medicine;- repeat TKA;- 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) |

**Primary purpose:** Treatment

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2015 |
| Enrollment: | 90 |
| Type: | Anticipated |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | ropivacaine |
| Generic name: | ropivacaine |
| Registration: | Yes - NL intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 31-03-2015 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 22-04-2015 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22055
Source: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2014-005596-90-NL |
| CCMO | NL51548.100.15 |
| OMON | NL-OMON22055 |