

# Effect of intra- and postoperative strategy of pain management on functional outcome in patients subjected to knee arthroplasty.

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A combination of sciatic nerve blockade (single shot or continuous blockade) with continuous regional blockade of the femoral nerve will improve short and long term functional outcome as well as patient satisfaction after total knee arthroplasty.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON24222

### Bron

NTR

### Verkorte titel

Regional analgesia after TKA

### Aandoening

patients subjected to total knee arthroplasty

### Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC) Department of Anesthesiology

**Overige ondersteuning:** fund=initiator=sponsor

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Reaching of discharge criteria:

1. 90 degree flexion of the knee;<br>
2. No infection;<br>
3. Pain on the visual analogue scale (VAS) lower than 4 (scale 0-10).

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

A Clinical Pathway for patients subjected to knee arthroplasty has been introduced in the Academic Medical Center Amsterdam AMC. In a multidisciplinary group including every department contributing to the clinical pathways of these patients, all aspects of pre-, intra-, and postoperative care including facilities at home have been discussed. Regarding anesthesiologic care, one major point is the best possible postoperative pain management and the influence of postoperative pain on long-term functional outcome. This topic shall be addressed in the current study.

Objective:

The aim of this clinical study is to investigate whether a combination of sciatic nerve blockade (single shot or continuous blockade) with continuous regional blockade of the femoral nerve will improve short and long term functional outcome as well as patient satisfaction after total knee arthroplasty.

Study design:

Single center, prospective, randomized controlled study.

Study population:

Patients subjected to total knee arthroplasty, age older than 18 years, American Society of Anesthesiologists (ASA) classification I to III.

Intervention:

In patients subjected to total knee arthroplasty post-operative pain therapy will be provided by patient controlled analgesia via femoral nerve blockade with or without single shot or continuous sciatic nerve blockade.

Main study parameters/endpoints:

Primary endpoint:

Reaching of discharge criteria (90 degree flexion of the knee, no infection, pain on the visual analogue scale (VAS) lower than 4 (scale 0-10)

Secondary endpoints:

1. Functional results at discharge and after 3 months and one year after the operation;
2. Analgesic consumption: Use of morphine and tramadol, pain measured by VAS postoperatively on day 0, 1, 2 and 3 during rest and movement, respectively;
3. Postoperative nausea and vomiting (PONV, 0: absence, 1: mild, 2: severe);
4. Effect of removing catheters on functional aspects (loss of functional capacity after removing catheters);
5. Patient overall satisfaction (measured using the Oxford knee questionnaire, a score with good reliability, content validity and construct validity in patients subjected to TKA<sup>15;16</sup>) Patient satisfaction with regional blockade procedure (school marks);
6. Time necessary to place catheters;
7. Amperage of stimulation of motor response;
8. Onset of motor and sensory block.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Sciatic blockade, in particular its motor consequences, might obscure diagnosis of perioperative sciatic nerve injury due to surgical incidences during the operation. Sciatic nerve injury after TKA has an overall incidence of 0.2 to 2.4%. However, addition of sciatic nerve blockade might be more effective for pain relief after TKA compared to femoral blockade alone. No additional burden is expected as clinically used routine pain management strategies are compared with each other.

## **Doel van het onderzoek**

A combination of sciatic nerve blockade (single shot or continuous blockade) with continuous regional blockade of the femoral nerve will improve short and long term functional outcome as well as patient satisfaction after total knee arthroplasty.

## **Onderzoeksopzet**

1. During stay of hospital;

2. 3 months after operation;

3. 1 year after operation.

### **Onderzoeksproduct en/of interventie**

In patients subjected to total knee arthroplasty post-operative pain therapy will be provided by patient controlled analgesia via femoral nerve blockade with or without single shot or continuous sciatic nerve blockade.

## **Contactpersonen**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

1. Informed consent;

2. American Society of Anesthesiologists (ASA) classification I to III;

3. Age older than 18 years.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. No informed consent;
2. ASA classification IV or V;
3. Infection near the insertion site;
4. Coagulation disorder, allergy to local anesthetics;
5. Pre-existing neurologic deficit of the operated leg;
6. Prior vascular surgery near the insertion site;
7. Inability to understand the patient controlled analgesia device;
8. Pregnancy or lactation period;
9. Known hepatic or renal insufficiency;
10. Age 18 years or younger.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### **Deelname**

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2008

Aantal proefpersonen: 90  
Type: Verwachte startdatum

## Ethische beoordeling

Positief advies  
Datum: 09-02-2010  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL2090
NTR-old	NTR2207
Ander register	MEC Academic Medical Center : 07/321
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

N/A