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

No registrations found.

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

Summary

ID

NL-OMON24222

Source
NTR

Brief title
Regional analgesia after TKA

Health condition

patients subjected to total knee arthroplasty

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Department of Anesthesiology
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Reaching of discharge criteria:

1. 90 degree flexion of the knee;

2. No infection;

3. Pain on the visual analogue scale (VAS) lower than 4 (scale 0-10).

Secondary outcome

1. Functional results at discharge and after 6 weeks and one year after the operation;

2. Analgesic consumption: use of morphine and tramadol;

3. Pain measured by VAS postoperatively on day 0, 1, 2 and 3 during rest and movement, respectively;

4. Postoperative nausea and vomiting;

5. Effect of removing catheters on functional aspects (loss of functional capacity after removing catheters);

6. Patient overall satisfaction (measured using the Oxford knee questionnaire, a score with good reliability, content validity and construct validity in patients subjected to TKA);

7. Patient satisfaction with regional blockade procedure (school marks);

8. Time necessary to place catheters;

9. Amperage of stimulation of motor response;

10. Onset of motor and sensory block.

Study description

Background summary

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 TKA15;16)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.

Study objective

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

1. During stay of hospital;

2. 3 months after operation;

3. 1 year after operation.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;

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

3. Age older than 18 years.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2010
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	NL2090
NTR-old	NTR2207
Other	MEC Academic Medical Center : 07/321
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A