Effect of intra- and postoperative strategy of pain management on functional outcome in patients subjected to total knee arthroplasty (TKA)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32063

Source
ToetsingOnline

Brief title
Regional anesthesia in total knee arthroplasty

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: femoral nerve block, knee arthroplasty, sciatic nerve block

Outcome measures

Primary outcome

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 outcome

1. functional results at discharge and after 6 weeks 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

Study description

Background summary

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.

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.

Intervention

Group A: ultrasound guided introduction of a stimulated femoral nerve catheter
Intraoperative pain therapy: levo-bupivacaine 0.375% 20 ml followed by continuous infusion of levo-bupivacaine 0.125% 10 ml/h starting 45 min after first injection
Postoperatively: levo-bupivacaine 0.125% patient controlled analgesia via the catheter (5 ml bolus, 30 min lock-out, basal rate: 6 ml/h)
Group B: ultrasound guided introduction of a stimulated femoral nerve catheter
Intraoperatively: levo-bupivacaine 0.375% 20 ml followed by continuous infusion of levo-bupivacaine 0.125% 10 ml/h starting 45 min after first injection
N. ischiadicus single shot, 20 ml levo-bupivacaine 0.375 %
Postoperatively: levo-bupivacaine 0.125% patient controlled analgesia via the catheter (5 ml bolus, 30 min lock-out, basal rate: 6 ml/h)
Group C: ultrasound guided introduction of a stimulated femoral nerve catheter
Intraoperatively: levo-bupivacaine 0.375% 20 ml followed by continuous infusion of levo-bupivacaine 0.125% 10 ml/h starting 45 min after first injection
Introduction of a stimulating catheter along sciatic nerve, 20 ml levo-bupivacaine 0.375 % via the catheter
Postoperatively: levo-bupivacaine 0.125% patient controlled analgesia via the femoralis catheter (5 ml bolus, 30 min lock-out, basal rate: 6 ml/h), continuous infusion of levo-bupivacaine 0.125% 10 ml/h via sciatic nerve catheter.

Study burden and risks

No additional burden is expected as clinically used routine pain management strategies are compared with each other

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Informed consent, American Society of Anesthesiologists (ASA) classification I to III, age older than 18 years

Exclusion criteria

no informed consent, ASA classification IV or V, infection near the insertion side, coagulation

disorder, allergy to local anesthetics, pre-existing neurologic dysfunction, prior vascular surgery near the insertion side, inability to understand the patient controlled analgesia device, pregnancy or lactation period, known hepatic or renal insufficiency, age < 18 years.

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):	01-02-2008
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL20054.018.07