Fast-track rehabilitation protocol for Total Knee Arthroplasty: A Randomized Controlled Trial comparing Local Infiltration Analgesia with Femoral Nerve Block

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38898

Source
ToetsingOnline

Brief title
Fast track TKA: LIA vs FNB

Condition

- Other condition

Synonym
total knee arthroplasty

Health condition

Pijnbestrijding bij primaire totale knieprothese

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: Fast track, Femoral nerve block, Local infiltration analgesia, Total knee arthroplasty

Outcome measures

Primary outcome

functional outcome after total knee arthroplasty measured with a performance battery consisting of three functional tasks: Timed-Up-And-Go test, Stair Climb Task en Six Minutes Walk Test. These tests are done: . pre-operatively, 2. when reaching discharge criteria, 3. three months post-operatively, 4. one year post-operatively

Secondary outcome

length of stay, time to reach discharge criteria, quantity and quality of mobilization during hospital stay, pain medication consumption postoperatively (during hospital stay and after hospital discharge), painscores at rest and during mobilization, patient satisfaction with analgesia and the fast track protocol, range of motion of the operated knee, functional outcome of the knee reported by the patient, fear of motion and quality of life.

Study description

Background summary

For an optimal and fast recovery after total knee arthroplasty (TKA), a fast track rehabilitation protocol has been developed. The literature is not yet conclusive about the optimal anesthetic technique for this protocol. The optimal technique should support fast mobilization, by giving good pain relieve, with minmal side effects such as nausea, drowsiness and muscle weekness. Is pain relieve is optimal, the patient molizes fast and lenth of stay is shortened. But does fast recovery lead to better functional outcome?

Study objective

The objective of this study is to determine whether either a femoral nerve block (FNB) or local infiltration analgesia (LIA) is a better anesthetic technique to achieve optimal functional outcome after one year in patients receiving a total knee arthroplasty and following a fast track rehabilitation protocol.

Study design

The study is designed as a prospective mono-centre observer blinded randomized controlled trial.

Intervention

Patients will receive a total knee replacement under spinal anesthesia and posterior capsule infiltration combined with either a femoral nerve block (FNB) or local infiltration analgesia (LIA).

Study burden and risks

Patients participating in this study will not be subjected to any additional risk other than the common risks for surgery of primary knee arthroplasty or the standard used anesthetic techniques. The will not be admitted earlier or longer to the hospital.

The patient will visit the hospital one extra time pre-operatively for baseline measures. During this visit there will be extensive time for extra explanation of the study. This will be better than doing the functional tests on the day of the operation (for ethical, safety and logistical reasons). Patients will receive an travel and parking costs reimbursement.

Furthermore the patients will visit the clinic at regular follow-up moments. Patients will do the functional tests when in the clinic for regular follow-up. The questionnaires and physical examinations of the knee will take 15 minutes together. The functional battery will take 30 minutes in total for each visit.

Participating in this research will take some extra time and effort from the

patient but brings very little extra burden.

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

• age 50-80 years
• ASA physical health classification I - II
• patient presents with non-inflammatory primary knee osteoarthritis (radiological confirmation)
• patient planned for a primary unilateral posterior-stabilized tri-compartmental cemented total knee replacement (Genesis II - PS)
• scheduled for fast-track protocol TKA
• patient plans to be available for follow-up through one year postoperative

• written informed consent

Exclusion criteria

• any contra-indication for regional anesthesia
• any contra-indication for spinal anesthesia
• traumatic osteoarthritis requiring TKA
• an active, local infection or systemic infection
• known hypersensitivity to amide-type local anesthetics
• known hypersensitivity to opioids
• a Body Mass Index (BMI) > 40 kg/m2
• inability to walk independently (inability to walk at least 10 consecutive meters without a walking aid)
• scheduled for contralateral TKA within 1 year post-operative
• scheduled for another operation within 3 months post-operative
• physical, emotional or neurological conditions that would compromise compliance with postoperative rehabilitation and follow-up
• chronic opioid analgesic therapy
• rheumatoid arthritis

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2013
Enrollment:	80

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Epinephrine
Generic name:	Epinephrine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ropivacaine
Generic name:	Ropivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-06-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	18-09-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
EudraCT	EUCTR2013-001008-13-NL
CCMO	NL43965.072.13

Study results

Date completed:	22-12-2015
Actual enrolment:	82