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Effects of a continuous adductor canal block (ACB) added to local infiltration anesthesia (LIA) on pain and ambulation after total knee arthroplasty (TKA)

Submission date
21/10/2016

Recruitment status
No longer recruiting

Registration date
27/10/2016

Overall study status
Completed

Last Edited
04/10/2017

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
A knee joint replacement is a common procedure where the weight bearing surfaces of the knee joint are replaced with metal and plastic components to relieve pain and disability, most commonly caused by osteoarthritis (a type of arthritis where the surface of joints wears away, causing pain and stiffness). After this type of surgery patients often experience severe pain in the operated knee and need to take strong pain medications. The best known predictor for a good outcome after a total knee joint replacement is being able to move the knee joint soon after surgery (early knee mobilization) but this can be difficult to achieve if the patient is in too much pain. It is therefore important to improve pain management after this type of surgery so that patients are able to move sooner. Adductor canal block (ACB) is a where a numbing solution is injected into the leg to numb the nerve which alerts the brain about pain in the knee. The aim of this study is to find out whether use of ACB in the 48 hours after surgery can help patients to move sooner and experience less pain.

Who can participate:
Patients aged between 50 and 90 years old who are having a total knee replacement.

What does the study involve:
Participants are randomly allocated to one of two groups. Those in the first groups receive an ACB, which involves having a drug called ropivacaine 0.2% injected into the inner thigh to numb the nerve that sends pain signals from the knee to the brain. Those in the second group are injected with normal saline (salt water), which does not have any effect (dummy drug). In both groups, patients are given an initial dose of 20ml after surgery, followed by being given a continuous flow through a drip of 6ml/h for 48 hours. Participants in both groups have their pain levels and movement abilities assessed by physiotherapists 24 and 48 hours after surgery. In addition, participants are followed up until discharge to find out how long their stay in hospital lasts for and if they experience any complications.

What are the possible benefits and risks of participating:
Patients could possibly benefit from better better pain management after the surgery if they receive the ACB. There is a small risk of infection or irritation from the tube placed in the leg to administer the study drugs. There is also a small risk of nausea and vomiting, low blood pressure and racing heartbeat for participants who receive ropivacaine.

Where is the study run from:
Akureyri Hospital (Iceland)

When is study starting and how long is it expected to run for?
May 2015 to June 2016

Who is funding the study?
1. Science fund of Akureyri Hospital (Iceland)
2. Science fund of the physicians council of Akureyri Hospital (Iceland)

Who is the main contact:
Svava Gudmundsdottir
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Contact information

Type(s)
Public

Contact name
Miss Svava Gudmundsdottir

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3/2015

Study information

Scientific Title

A randomised, double-blind, placebo-controlled trial with 69 patients on the effects of a continuous adductor canal block (ACB) added to local infiltration anesthesia (LIA) on pain and ambulation after total knee arthroplasty (TKA)

Study objectives
A continuous adductor canal block (ACB) added to a single-dose local infiltration anaesthesia (LIA) would lower pain scores while ambulating on Postoperative Day 1 (POD1) and Postoperative Day 2 (POD2).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of the Akureyri Hospital and the Icelandic Data Protection Authority, 25/08/2015, ref: 3/2015

Study design
Single-centre double-blind randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Pain management after total knee arthroplasty

Interventions
All eligible patients are sent a letter with information about the study. At the preoperative assessment the patients sign the written consent if they wish to participate and at the same time demographic and preoperative data will be collected (age, height, weight, BMI, gender, race, pain medication use and ASA-score). Participants are then randomised to one of two groups using a computer-generated randomization list (Research randomizer, www.randomizer.org) in a 1:1 ratio with 20 numbers in each block. Every participant is assigned a consecutive study-number from 1-69 and receives the treatment assigned according to the randomization list.

Intervention group: Participants receive 0.2% ropivacaine
Placebo group: Participants receive normal saline

Both groups (intervention and placebo) are given the study medication continuously through a catheter in the adductor canal at 6 ml/h for 48 hours after the total knee arthroplasty surgery.

Participants in both groups are followed up on postoperative days one and two at which time physiotherapists assess their pain and mobility levels. Participants also have their medical records reviewed upon discharge to record any adverse events and the length of their hospital stay.

Intervention Type
Procedure/Surgery

Primary outcome measure
Peak pain levels in the operated knee during morning physiotherapy session are measured using a Numeric Rating Scale (NRS) on postoperative day 1 and postoperative day 2.

Secondary outcome measures
1. Pain at rest was assessed using a numerical rating scale (NRS) before the morning physiotherapy session on postoperative day 1 and 2
2. Total pain medication used by the patient from the time of admission until 48 hours after the surgery is registered and calculated into oral morphine equivalent by reviewing the patients' medical files from the medication database "Therapy" used by Akureyri Hospital to register patient's medications 48 hours after admission
3. Total use of antiemetics (metoclopramide, ondansetron, haloperidol and dexamethasone) is gathered by reviewing the patient's medical files from the medication database from the drug database "Therapy" used by Akureyri Hospital to register patient's medications 48 hours after admission
4. Mobility is assessed using the Timed Up and Go (TUG) test on the morning of postoperative day 2
5. Actual length of hospital stay is recorded by reviewing patient's medical files right after discharge
6. Time from the end of surgery until additional pain medication is given is gathered from the medication database "Therapy" used by Akureyri Hospital to register patient's medications at the time of discharge
7. Time taken for patient to meet ready for discharge criteria following knee replacement surgery (able to walk with crutches, use only oral analgesia, bend the operated knee ≥70°, climb stairs and had no acute medical problems present) is measured by reviewing medical records at the time of discharge
8. Quadriceps muscle strength is assessed by the ability of the patient to hold the affected limb up with the knee extended against resistance of the examiner (using manual muscle testing (MMT) with 0= no contraction, 1= flicker of contraction, 2= active movement with gravity eliminated, 3= active movement against gravity but not resistance, 4= active movement against gravity and some resistance and 5= normal strength) in the morning of postoperative day 1 and 2
9. Nausea is assessed on a 5-point scale (0= no nausea, 1= mild, 2= moderate, 3= severe, and 4= vomiting episode) in the morning of postoperative day 1 and 2
10. Goals of ambulation are measured by using the 10-point mobility scale by the physiotherapists in the morning physiotherapy session of postoperative day 1 and 2
11. Straight leg raise is assessed by asking the patient to hold his lower limb 10 cm from the bed with fully extended knee for 10 seconds in the morning of postoperative day 1 and 2
12. Flexion of the knee is assessed using a clinometer in the morning of postoperative day 1 and 2.
13. Falls of patients are recorded by reviewing the patients' medical files after discharge

14. Toxic effects of the ropivacaine (nausea, vomiting, hypotension and bradycardia) are observed by the nurses of the ward while the participants had the adductor canal catheter every morning and during routine follow up by the nurses and through measuring vitals every 4-6 hours during the entire hospital stay
15. Drainage of blood in the drainage is measured (in ml) when the drainage was removed in the morning of postoperative day 1
16. Blood transfusion rate is recorded in the patient medical files by the time the patient was discharged

Overall study start date
01/05/2015

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Patients scheduled for primary unilateral cemented TKA under spinal anesthesia
2. Aged 50 – 90 years
3. With American Society of Anesthesiologists (ASA) physical status I-III

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
69 patients in total, 35 in the intervention group and 34 in the placebo group.

Key exclusion criteria
1. Daily intake of opioids (20 mg/day of oral morphine equivalent for > 12 weeks)
2. Inability to cooperate
3. Peripheral neuropathy
4. Allergy to any of the study medications
5. Renal insufficiency (creatinine levels > 100 µmol/L and > 110 µmol/L for women and men respectively)

Date of first enrolment
01/10/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Iceland

Study participating centre
Akureyri Hospital
Eyrarlandsvegur
Akureyri
Iceland
600

Sponsor information

Organisation
Akureyri Hospital

Sponsor details
Eyrarlandsvegur
Akureyri
Iceland
600

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0028r9r35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Science fund of Akureyri Hospital (Vísindasjóður Sjúkrahússins á Akureyri)

Funder Name
Science fund of the physicians council of Akureyri Hospital (Vísindasjóður Læknaráðs, Sjúkrahússins á Akureyri)

Results and Publications

Publication and dissemination plan
Planned publication in Acta Orthopaedica.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
All data gathered during the trial is safely stored at Akureyri Hospital in Akureyri Iceland. This includes the filled out form for every single participant (“patient form” attached in the email), written informed consent from all the participants, all the statistical calculations and the randomization key. Only Svava Gudmundsdottir (svava85@gmail.com) and Jonas Franklin have access to the files which are stored in Akureyri Hospital. To request access please contact through email. The files will be stored for total of 10 years from September 2016 - September 2026.
Written informed consent was obtained from all the participants and those are stored with the files in Akureyri Hospital. Every participant received a consecutive study number from 1 to 69 and received the treatment assigned according to the randomization list. The randomization key was first broken when all enrolled patients had completed the study. After discharge, the participant’s personal information was eliminated from the study number and is therefore not traceable back to the patient. All the data from every participant (“patient form”) is therefore anonymous but the informed consent is signed and is therefore not anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		24/10/2016	23/11/2016	No	Yes
Results article	results	01/10/2017		Yes	No