Efficacy of Adductor Channel Block for anterior cruciate ligament surgery: A prospective double blinded randomized controlled trial

Published: 02-06-2022
Last updated: 06-04-2024

The goal of this study is to objectify the postoperative pain level, the use of opiates and postoperative nausea and vomiting after adding the adductor channel block to the standard pain regiment after anterior cruciate ligament surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON51570

Source
ToetsingOnline

Brief title
DUAL trial

Condition

- Tendon, ligament and cartilage disorders

Synonym
anterior cruciate ligament rupture

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Bijdrage R&D anesthesiologie

Intervention

Keyword: Adductor channel block, Anterior cruciate ligament surgery, locoregional anesthesia

Outcome measures

Primary outcome

The primary endpoint is postoperative pain (numerical rating score) within the

first 24 hours

Secondary outcome

Secondary endpoints are pain score 48 hours postoperative, motor block result,

use of postoperative pain medication including opiates and the use of rescue

medication, postoperative pain location, postoperative nausea and vomiting, use

of anti-emetics, overall patient satisfaction, contact within 48 hours after

surgery with general practicioner or emergency department and adverse events.

Study description

Background summary

Addition of locoregional anesthesia to the standard, multimodal pain management reduces postoperative pain after knee surgery. Locoregional blockade of the femoral nerve provides adequate pain relief after knee surgery but can induce weakness of the quadriceps muscle as an adverse event. Blocking the saphenous nerve, the vastus medialis nerve and the medial femoral cutaneous nerve ocasionally with the anterior skin branch of the obturator nerve, known as the *adductor channel* is a simple and effective technique to reduce postoperative pain after knee surgery.

Study objective

The goal of this study is to objectify the postoperative pain level, the use of opiates and postoperative nausea and vomiting after adding the adductor channel

block to the standard pain regiment after anterior cruciate ligament surgery.

Study design

Prospective, double blinded randomized intervention study.

Intervention

Identification of the adductor channel using ultrasonic landmarks such as the femoral artery and the sartorius muscle. When a patient is randomized in the intervention group; 10 ml of Levobupivacaine 0.25% will be added in the adductor channel. When randomized in the control group: 10 ml of sodium chloride 0.9% (placebo) will be added in the adductor channel.

Study burden and risks

Locoregional anesthesia is an existing and well recognized method to relieve perioperative and postoperative pain. Addition of locoregional anesthesia to the standard, multimodal pain regimen will reduce postoperative pain and use of pain medication after knee surgery. Patients will be randomized between the control group (placebo injection with sodium chloride 0.9% solution) or the adductor channel block with levobupivacaine 0.25%. After induction, study patients will either receive a placebo injection of the adductor channel block or with levobupivacaine. The ultrasonic landmarks (femoral artery and sartorius muscle) are easily recognizable using ultrasound. The risks of the adductor channel block are limited and are being minimalized by the use of ultrasound. Known adverse events are infection, bleeding, intravascular administration and temporary motor block.

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

- ASA classification 1-3
- Age >= 18 years
- Anterior cruciate ligament surgery
- General anesthesia
- Informed consent

Exclusion criteria

- Contraindication to local anesthetics
- Neuromuscular disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2022
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80947.100.22
Other	volgt

Study results

Date completed:	01-10-2023

Actual enrolment:	34