SaphenoUs Nerve block Reduces length of Stay after Epiphysiodesis of the knee - a triple blind randomised superiority trial

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Objective: The primary outcome objective of this trial will be length of stay in the hospital after surgery. We further will analyze intra- and postoperative opioid consumption, NRS pain scores, time in the post anesthetic care unit, time to walk (...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46475

Source
ToetsingOnline

Brief title
SUNRiSE

Condition

- Bone and joint therapeutic procedures

Synonym
Epiphysiodesis - operation to stop the growth plate of the knees te prevent excessive hights

Research involving
Human

Sponsors and support

Primary sponsor: Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: epifysiodesis, length of stay, nerve block, opiate consumption

Outcome measures

Primary outcome

Main study endpoints: The main study endpoint is the reduction in postoperative

length of hospital stay measured in hours after leaving the post-anesthetic

care unit.

Secondary outcome

intra- en postoperative opioid consumption

NRS pain score

time in the post anesthetic care unit

time to walk (with crutches)

muscle strength (M. quadriceps)

overall patient satisfaction

Study description

Background summary

Rationale: Percutan epiphysiodesis of the genual growth plates is a routinely performed surgery in the pediatric orthopedic department of the Wilhelmina Hospital Assen in the Netherlands. We hypothesize that a single shot saphenous nerve block in combination with general anesthesia would be superior to general anesthesia alone regarding opioid consumption, pain scores, recovery and length of stay.

Study objective

Objective: The primary outcome objective of this trial will be length of stay in the hospital after surgery. We further will analyze intra- and postoperative opioid consumption, NRS pain scores, time in the post anesthetic care unit,

time to walk (with crutches), strength of the quadriceps muscle and overall patient satisfaction as secondary outcome measures.

Study design

Study design: The study will be randomized, placebo-controlled triple blind: anesthesiologist and orthopedic surgeon as well as the patient, all nurses taking care of the patient and physiotherapist are blinded.

Intervention

Intervention: All patients of the interventional group receive bilateral saphenous nerve block with 10ml of Ropivacaine 0,5% for each leg. The placebo group will receive saphenous nerve block with Sodiumchloride 0,9%. Both groups will than undergo general anesthesia and standardized postoperative analgesics.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As the epiphysiodesis of the knee can only take place once the growth plates are still open and active it is evident, that this study enrolls patients in their teenage years. None of the possible risks like allergic reaction to Ropivacaine, cardiotoxic or central nervous effects following intravascular injection, local anesthetic systemic toxicity (LAST) after overdosing, hematoma of deeper structures such as muscles, nerve damage of muscle weakness have been observed in the pilot study. The expected benefits for patients undergoing epiphysiodesis of the knee like earlier discharge from the hospital, less opioid consumption, less PONV, reduced time in the post-anesthetic care unit and reduced pain scores shall outweigh the risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

ASA 1-2
age 12-18
informed consent patient/ parents
bilateral operation (both knees)

Exclusion criteria

chronic pain killers in use
other surgical procedures within the same period
medical conditions not in line with operation that need a longer stay in hospital

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:	Will not start
Enrollment:	44
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	15-12-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22187
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64631.042.18
OMON	NL-OMON22187