

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

Published: 09-10-2018

Last updated: 15-05-2024

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 (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	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 highs

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Wilhelmina Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** epiphyseodesis, 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 epiphyseodesis of the genu 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 then 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: NTR

Title:

### In other registers

Register	ID
CCMO	NL64631.042.18
OMON	NL-OMON22187