Postoperative pain treatment following surgical intervention of the epifyse

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24503

Source
Nationaal Trial Register

Brief title
Postoperative pain treatment follwing epiphysiodesis

Health condition

postoperative pain following an epiphysiodesis procedure of both legs for adolescents

Sponsors and support

Primary sponsor: Raad van bestuur Maxima Medisch Centrum
Source(s) of monetary or material Support: Cooperatie Orthopedie Groot Eindhoven

Intervention

Outcome measures

Primary outcome

Number rating scale for pain during the first 5 days postsurgery

Secondary outcome

Number rating scale for pain at other follow-up measurements; co-medication use; adverse

events; satisfaction score of the patient; hospital stay and KOOS

Study description

Study objective

The hypothesis is that an epidural pain treatment for adolescents is more effective as postoperative pain treatment following an epiphysiodesis procedure compared to a post operative pain treatment with intraveneus PCA method.

Study design

Primary outcome: day 1-5 postsurgery

Secondary outcome: at 2 weeks, 6 weeks and 6 months

Intervention

a) epidural pain management: bupivacain 5mg/hour pump according to pain protocol for children of Máxima Medical Centre. The epidural pain protocol will be started at the beginning of the surgical procedure and will be 3 days in situ.

b) pain medication by intravenous PCA (pain pump): morfine 1mg/ml by pump with lockout time of 6 minutes and additional bolus of 1/2mg vaccording to pain protocol for children of Máxima Medical Centre.

Contacts

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Eligibility criteria

Inclusion criteria

Patients should meet the following inclusion criteria: age between 12-16 year; “indication for epiphysiodesis”, namely boys for which the estimated final body length will be minimally 200 cm; for girls this will be 195 cm.

Exclusion criteria

A patient should not meet the following exculison criteria: insufficient command of Dutch language; niet willing to participate; contraindications for surgery.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-05-2015
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42155
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5064
NTR-old	NTR5195
CCMO	NL50837.015.15
OMON	NL-OMON42155

Study results