Epifysiodesis for adolescents; What is the most effective postoperative pain treatment? An RCT

Published: 23-03-2015
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What is the effectiveness of an epidural painmanagement compared with a PCA method as postoperative treatment after an epiphysiodesis for adolescents during the first 5 days after the procedure?

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON42155

Source
ToetsingOnline

Brief title
Postoperative pain treatment after epiphysiodesis

Condition

- Bone disorders (excl congenital and fractures)

Synonym
postoperative pain; pain after epiphysiodesis

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Maatschap Orthopedie

Intervention

Keyword: adolescent, epiphysiodesis, pain treatment, RCT

Outcome measures

Primary outcome

The primary outcome is the VAS (visual analoge scores) for pain during the

first 5 days after the procedure.

Secondary outcome

Secundary outcome measures are: amount of pain 2 weeks , 6 weeks and 6 months

after the procedure; co-medication use; adverse events; satisfaction rate of

the patient; duration of Hospital stay and knee function.

Study description

Background summary

An epiphysiodesis of the knee is a frequently performed procedure for adolescents in Maxima MC. Since three year both departments of Orthopedic surgery of Maxima MC and Catharina Hospital has formed one membership, and as consequent from this there are two different postoperatiev pain management protocls active. Namely a) an epidural pain protocol and b) a PCA (pain pump). Both painmanagement protocol will be compared.

Study objective

What is the effectiveness of an epidural painmanagement compared with a PCA method as postoperative treatment after an epiphysiodesis for adolescents during the first 5 days after the procedure?

Study design

open-labeled randomized clinical trial

Intervention

a) epidural painmanagement will be started at the beginning of the surgical procedure and will be in situ for three days. Thereafter painmedication will be prescribed according to the WHO; b) painmanagement with the use of a PCA (pain pump) started directly after the surgical procedure, eventually oral medication according to the WHO will be given.

Study burden and risks

Both pain management protocols are currently used in Maxima MC. The VAS is used as standard evaluation tool during the Hospital period. During the standard visits of the outpatient clinic we ask additional time of the patient to fill in two questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

age between12-16 year; *indicated for an epiphysiodesis*, namele boys of which the estimated finally body length will be minimally 200 cm; and for girls 195 cm.

Exclusion criteria

insufficient command of Dutch language; not willing to be randomized; contra-indications for an epiphysiodesis procedure.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-10-2015
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bupivacaïne Actavis
Generic name:	Bupivacaïne
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Morfine HCl CF
Generic name:	Morfine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-03-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-03-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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: 24503
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-000870-36-NL
CCMO	NL50837.015.15
OMON	NL-OMON24503

Study results

Date completed: 15-02-2017

Summary results
Trial ended prematurely