Comparison of different doses of levobupivacain for caudal block in children undergoing hypospadia repair.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20616

Source
NTR

Brief title
N/A

Health condition

Caudal analgesia, hypospadia, levobupivacaine

Sponsors and support

Source(s) of monetary or material Support: Abbott NL provided levobupivacaine free of charge

Intervention

Outcome measures

Primary outcome

Duration of analgesia.

Secondary outcome

Motorfunction.

Study description

Background summary

Background:
Despite the increasing use of Levobupivacain in children there are currently no data available on the duration and quality of caudal analgesia in a homogenous paediatric patient group undergoing a hypospadia repair.

Goal of the study:
To assess the design of a dose-effect of study of Levobupivacain for caudal analgesia and to obtain preliminary data for a power analysis in children undergoing hypospadia repair.

Method:
Twenty patients median age 17 months, median weight 10.5 kg were allocated to two groups receiving either 0.5 ml/kg Levobupivavcain 0.125% (Group 0) or 0.5ml/kg Levobupivacain 0.375% (Group 1) caudally for hypospadia repair after induction of anaesthesia with sevoflurane and rocuronium. No further analgesia was given before, during or after the procedure. Pain scores (CHIPPS) were recorded throughout the observation period, which lasted from the start of the procedure until hospital discharge on the following day.

Results:
Group 0: six out of ten patients remained pain free throughout the observation period.
Group 1: six out of seven patients remained pain free throughout the observation period.

Discussion:
Both concentrations of Levobupivcaine provided excellent analgesia throughout surgery. The study design is feasible, but given the surprisingly long lasting analgesia we have found in both groups, the observation period needs to be extended.

Conclusion:
The duration of analgesia after caudal block with Levobupivacaine was found to be significantly longer lasting than previously reported.

Study objective

N/A

Study design

Observation period: until hospital discharge on the first post-op day.

Intervention

1. Group 0:0.5 ml/kg levobupivacaine 0.125% caudally;

2. Group 1: 0.5 ml/kg levobupivacaine 0.375% caudally
before surgery commenced.

Contacts

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Eligibility criteria

Inclusion criteria

Children between the age of six month and four years undergoing hypospadia repair.

Exclusion criteria

Severe co-morbidity: ASA 3 & 4.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2005
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	09-02-2009
Application type:	First submission

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
NTR-new	NL1589

Register	ID
NTR-old	NTR1669
Other	CCMO/UMC St Radboud AMO : P03.1389C/04/068
ISRCTN	ISRCTRN wordt niet meer aangevraagd

Study results

Summary results
N/A