Levobupivacaine for pediatric caudal block. Comparison of three different dose in children undergoing hypospadia repair: a double-blinded randomised study

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To determine the best doses-respons of levobupivacaine for postoperatief analgesia after caudal anesthesia for hypospadia repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urethral disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON30036

Source
ToetsingOnline

Brief title
Doubleblinded randomised study: levobupivacaine caudal injected in child.

Condition

- Urethral disorders (excl calculi)

Synonym
hypospady, wrong exit urthra

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: caudal block, double-blinded, levobupivacaine, pediatric

Outcome measures

Primary outcome

Pain will be assessed at predetermined points with the Children and Infants Postoperative Pain Scale (CHIPPS). At a score > 3 rescue medication will be administered. Furthermore, the time interval until children are able to move their legs and stand, will be registered. The observation period is 24 hours.

Secondary outcome

Discharge from hospital

rehospitalisation after discharge due to pain

Study description

Background summary

Comparison of three different doses of levobupivacaïne for caudal block in children undergoing hypospadia repair.
A dubbelblind randomised study

Levobupivaca*ne is less cardiotoxic and therefore has a wider therapeutic range than Bupivaca*ne, while exhibiting comparable analgetic properties. Still, there is little data on the dose-effect relationship of Levobupivaca*ne in children. The aim of this prospective study was to investigate the duration of analgesia and motor blockade of three different doses of Levobupivaca*ne for a caudal block in children undergoing hypospadia repair and to determine the optimum dosis- effect result.

Study objective

To determine the best doses-respons of levobupivacaine for postoperatief analgesia after caudal anesthesia for hypospadia repair.

Study design

Prospective doubleblind randomized of studydesign.
After standard general anesthesia seventyfive childeren receive caudal anesthesia for postoperative painrelief. 3 group of 25 patiënten.
Groep A: CA with 0,5ml Levobupivacaine 0,125%/kg bodywight
Groep B: CA with 0,5ml Levobupivacaine 0,250%/kg bodywight
Groep C: CA with 0,5ml Levobupivacaine 0,375%/kg bodywight

Study burden and risks

There will be no risk for our patients. We expect a reduction of risk because levobupivacaine is less cardiotoxic than bupivacaine. Because the frequency of painmonitoring we also expect more quality of care.

Contacts

Public
Academisch Medisch Centrum

geert grooteplein 10
6500 hb
Nederland
Scientific
Academisch Medisch Centrum

geert grooteplein 10
6500 hb
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

childeren in age of 6 month till 4 years, receving hypospadiacorrection. informed consent by the parents

Exclusion criteria

illness or medication influencing the bloodclotting, vasculopathy, thrombopathy, allergic for local anesthetics

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	75
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	chirocaine

Generic name:	levobupivacaine hcl
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-06-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2006-002291-17-NL
CCMO	NL12213.091.06