Pharmacokinetics and pharmacodynamics of Acetaminophen in neonates.

No registrations found.

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

Summary

ID

NL-OMON24744

Source
Nationaal Trial Register

Brief title
PARANEOPAIN

Health condition

Neonates, Paracetamol intravenous, Pharmakokinetics, Pharmacodynamics

Sponsors and support

Primary sponsor: Erasmus Medical center, Sophia Children's Hospital
Source(s) of monetary or material Support: Erasmus Medical center, Sophia Children's Hospital

Intervention

Outcome measures

Primary outcome

Pharmacokinetic properties of Acetaminophen in neonates: Safety and Efficacy Profile: Determine optimal loading dose of Acetaminophen in different age-subgroups.

1. Safety outcome parameters are:

A. Acetaminophen serum levels;

B. Acetaminophen metabolite levels in urine samples;

C. Renal function;

D. Hepatotoxicity (determine NAPQ1levels as indicator).

2. Pharmacodynamic properties of Acetaminophen in neonates: Comfortneo score and PIPP as pain assessment tools used in the different dose regimens of acetaminophen.

Secondary outcome

Registration and/or drug interaction:

1. Influence of drugs metabolised by cytochrome P-450 on serum levels of acetaminophen: indomethacin;

2. Influence of acetaminophen on indomethacin-treatment of PDA closure;

3. Influence of acetaminophen on bilirubin glucuronidation.

Study description

Background summary

Acetaminophen is the most common used analgesic and antipyretic drug in children and even prescribed in neonates to treat mild to moderate pain. Administered in therapeutic doses it is deemed to be safe, but only limited data are available of intravenous acetaminophen in term and preterm infants.

In this prospective blinded randomised trial, open-label, dose –finding all neonates (preterm and term) stratified by age groups admitted within the first 24 hours of life to the NICU with an indwelling arterial catheter for clinical purpose, are allocated to a specific dose regimen of intravenous acetaminophen (10mg/kg, 15 mg/kg or 20 mg/kg).

Study objective

To test the hypothesis that acetaminophen is a safe and effective analgesia in neonates and to determine the optimal loading dose of intravenous Acetaminophen in neonates of different gestational age subgroups.

Study design

All neonates (preterm and term) stratified by age groups admitted within the first 24 hours of life to the NICU with an indwelling arterial catheter for clinical purpose, undergoing at least one painful procedure in the first 7 days of life.

Intervention

Patients will be randomly allocated to a specific dose regimen of intravenous acetaminophen (10mg/kg, 15 mg/kg or 20 mg/kg) when they need to endure a painful procedure (i.v placement, insertion of a peripheral venous line) in the first week after birth.

Contacts

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Eligibility criteria

Inclusion criteria

1. Neonates (in- and outborn) with a gestational age of 24-42 weeks;

2. Admission within the first 24 hours of life;

3. Indwelling arterial catheter;

4. Painful procedures within the first week of life;

5. Informed consent of the parents or legal guardian.

Exclusion criteria

1. Major congenital anomalies;

2. Intraventriculair haemorrhage > grade 2;

3. Neuromuscular blockers;

4. Absence of an indwelling catheter;

5. Use of morphine, midazolam at start of the study; If patients received more than one loading dose of morphine or midazolam prior to the study or in need of maintenance of any painkiller during the study, they are excluded from participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	12-04-2010
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	NL2166
NTR-old	NTR2290
Other	MEC Erasmus MC : 2009-250
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A