

Morphine intravenous vs. paracetamol intravenous after cardiac surgery in neonates and infants.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25142

Source

Nationaal Trial Register

Brief title

PACS (Pediatric Analgesia after Cardiac Surgery)

Health condition

Cardiac Surgery
Congenital Cardiology
Pain
Morphine
Paracetamol
Pharmacokinetics
Pharmacodynamics

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam

Source(s) of monetary or material Support: ZonMW, goed gebruik geneesmiddelen programma

Stichting Vrienden van het Sophia

Intervention

Outcome measures

Primary outcome

Cumulative morphine dose over 48 hours in mcg/kg.

Secondary outcome

1. Incidence of adverse drug reactions
 - a. hemodynamically: hypotension or bradycardia, with the need for intervention by means of medication or a fluid bolus.
 - b. Decreased gastro-intestinal motility or intestinal obstruction not directly related to the underlying diagnosis and not previously existing, with the need for intervention.
 - c. Vomiting.
 - d. Number of re-intubations.
 - e. Pediatric delirium as measured by the SOS-PD-scale.
2. Non-inferiority analysis of comparing patients with one or more NRS pain scores ≥ 4 between groups.
3. DNA analysis will be performed to evaluate the effect of gene polymorphisms on the PK of analgesic medication.
4. Concomitant use of sedatives.
5. The number of hours on ventilation.
6. The length of PICU stay.
7. Role of alarmins in the systemic inflammatory response (only at Wilhelmina Children's Hospital, UMCUtrecht).
8. To develop a population PKPD-based post-operative pain management algorithm based on the results of this trial.

Study description

Background summary

Morphine is the most used primary analgesic after cardiac surgery in neonates and children. However, morphine has short term and long term negative effects in children. Our hypothesis is that paracetamol IV is as effective as morphine as primary analgesic after cardiac surgery in neonates and infants.

Study objective

Intermittent IV paracetamol is effective as the primary analgesic drug in post cardiac surgery patients up to 3 years of age and that the use of IV paracetamol will reduce overall morphine requirements.

Study design

Inclusion takes place before cardiac surgery. Study medication will continue until 48 hours after cardiac surgery. Pharmacodynamic assessment will continue until 48 hours after study medication is stopped. Two days after discharge parents have a short telephone interview.

Intervention

1 arm will receive paracetamol IV intermittently, the other arm will receive morphine IV continuously. Both study drugs will be given double blind until 48 hours after cardiac surgery.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Informed consent,

Neonate / infant aged 0-36 months,

Cardiac surgery with the use of CPB.

Exclusion criteria

No informed consent

Known allergy to or intolerance for paracetamol or morphine,

Administration of opioids in the 24 hours prior to surgery.

Hepatic dysfunction defined as three times the reference value of ALAT/ASAT.

Renal insufficiency defined as Pediatric RIFLE category - injury, defined as estimated creatinine clearance reduced by 50% and urine output <0.5 ml/kg/h for 16 hours.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 15-12-2015
Enrollment: 204
Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47394
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5339
NTR-old	NTR5448
CCMO	NL53085.078.15
OMON	NL-OMON47394

Study results