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

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The aim of the study is to test the hypothesis that intermittent intravenous paracetamol administration in children after cardiac surgery will result in a reduction of at least 30% of the cumulative morphine requirement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON47394

Source
ToetsingOnline

Brief title
PACS; Pediatric Analgesia after Cardiac Surgery.

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
post-operative pain

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care Kinderen

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW- goed gebruik geneesmiddelen programma

Intervention

Keyword: Analgesia, Cardiac-surgery, Children, Sedation

Outcome measures

Primary outcome

The cumulative morphine consumption during the first 48 hours after cardiac

surgery.

Secondary outcome

Level of pain assessed by validated PD instruments until 48 hours after stop

study medication

Incidence of adverse drug reactions

Incidence of concomitant use of sedative

Hours on ventilation

Incidence of over- and undersedation

Incidence of withdrawal syndrome and pediatric delirium

The length of PICU stay

Use of corticosteroids

Parents postoperative pain measurement two days after discharge

Levels of cortisol and ACTH

Study description

Background summary

Adequate post-operative pain relief after cardiac surgery in children is mainly

achieved by opioids. However, worldwide dosing and kind of opioids used vary greatly, with morphine being the drug of first choice. Morphine has unwanted hemodynamically and respiratory side effects. Post cardiac surgery patients may therefore potentially benefit from a non-opioid drug for their pain relief. A previous study has shown that intravenous paracetamol is effective and opioid sparing in children after major non cardiac surgery. Intermittent intravenous administration of paracetamol may therefore result in a significant decrease in cumulative morphine consumption in the first 48 hours after cardiac surgery. Also, administration of opioids can influence the concentration of stress hormones after surgery. In the PACS study, half of the patients do not receive opioids. we will therefore measure stresshormones (cortisol and ACTH) in all patients participating in the PACS study as from september 2018 to study the influence of opioids.

Study objective

The aim of the study is to test the hypothesis that intermittent intravenous paracetamol administration in children after cardiac surgery will result in a reduction of at least 30% of the cumulative morphine requirement.

Study design

A prospective multi center randomized double blind study.

Intervention

Patients will be randomized to receive either intermittent intravenous paracetamol or continuous intravenous morphine up to 48 hours post-operatively. Morphine will be available as rescue medication for both groups.

Study burden and risks

The risks and burdens associated with this study are negligible. Blood samples are only taken from an indwelling arterial catheter, which is already in place for clinical purposes). Sedation and pain scores are observational procedures already performed for clinical purposes. Possible burden and risk of participating in the study is the risk of insufficient analgesia after cardiac surgery with intermittent intravenous paracetamol. Given previous studies on the postoperative efficacy of paracetamol in children after major non cardiac surgery, this risk is considered low. Moreover, morphine will be administered as rescue medication in case of insufficient analgesia in both groups.

Contacts

Public
Selecteer

Wytemaweg 80 80
Rotterdam 3015 CN
NL
Scientific
Selecteer

Wytemaweg 80 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2016
Enrollment:	156
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Morphine
Generic name:	Morphine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paracetamol
Generic name:	Paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	22-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-02-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 25142
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-001835-20-NL
CCMO	NL53085.078.15
OMON	NL-OMON25142

Study results

Date completed: 01-07-2021

Actual enrolment: 175

Summary results
Trial is onging in other countries