Intravenous Morphine versus intravenous Paracetamol in children on ECMO.

No registrations found.

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

Summary

ID

NL-OMON25353

Source
Nationaal Trial Register

Brief title
MAIVECMOPAIN

Health condition

Paediatric patients, Morphine iv, Paracetamol iv, ECMO, Critically ill Children, Pharmocokinetics, 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

Need for total morphine (ìg/kg/ECMO hour) in children included.

Secondary outcome

To compare in children on ECMO who receive either paracetamol IV boluses or morphine IV:

1. Number of extra morphine boluses required per patient;

2. The need for additional sedation/ analgetics;

3. Percentage of time that the patient is adequately pain free, based on validated and routinely obtained pain scores;

4. The incidence of opioid related adverse effects:

A. Vomiting;

B. Seizures without other demonstrable causes;

C. Opioid withdrawal symptoms assessed by SOS score and/or the need for prolonged morphine or methadone use;

D. Renal and/or CVVH clearance of paracetamol and glucuronidation and sulphate formation;

E. Pharmacogenetic markers (e.g. CYP polymorphisms).

To determine the PK-PD relationship for paracetamol IV and morphine in this population three blood samples are taken per day from an indwelling arterial line or from the ECMO circuit, with a total amount of 10ml /24 h (<3% of circulating volume without the ECMO circuit). Together with the blood samples, 10 mL urine and 10 mL dialysate samples are taken as well.

Study description

Background summary

Patients after treated with Extra Corporal Membrane Oxygenation (ECMO) receive morphine as pain relief medication whereas this is associated with morphine related side effects. In these patients a non-opioid drug could be appropriate for the postoperative pain relief of ECMO canula insertion and painrelief during ECMO treatment. Intermittent administration of intravenous acetaminophen, to children
during the ECMO run will lead to a 25% reduction in morphine requirements.

Study objective

To test the hypothesis that analgesia with paracetamol IV will lead to morphine-sparing when compared to standard morphine IV continuous infusion without paracetamol IV in children

(0-12Y) on ECMO.

Study design

Patients are followed during their ECMO treatment at the pediatric intensive care unit. After ECMO treatment and discharge a withdrawal score will be assessed using validated scores.

Intervention

Patients will be randomised in two groups:

1. Intermittent administration of paracetamol IV boluses + morphine rescue during ECMO treatment (intervention group);

2. Administration of a baseline morphine IV infusion + morphine rescue during ECMO treatment (control group).

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;

2. Neonate / child under 12y of age;

3. Minimal post conceptual age of 34 weeks;

4. Minimal body weight of 2000 grams;

5. ECMO treatment.

Exclusion criteria

1. Withdrawal of informed consent;

2. Known allergy / intolerance for acetaminophen or morphine;

3. Prolonged use of muscle blocking agents.

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):	25-01-2010
Enrollment:	52
Type:	Actual

Ethics review

Positive opinion

Date:	26-01-2010
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	NL2063
NTR-old	NTR2180
Other	METC Erasmus MC Rotterdam : MEC-2009-334
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A