Morphine vs. intravenous Acetaminophen after surgery in patients under the age of 1 year.

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Patients after non-cardiac thoracic or abdominal major surgery 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 postoperative pain...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26881

Bron
Nationaal Trial Register

Verkorte titel
MAIV

Aandoening

Analgesics
Acetaminophen
Perfalgan
Morphine
Pediatrics
Post operative

Post operatieve pijnbestrijding
kinderen
morfine
paracetamol

Ondersteuning

Primaire sponsor: Investigator initaited research
Prof. D. Tibboel, MD , PhD
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The absolute amount of morphine in mcg/kg/48 hours is the primary outcome measure.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY Morphine intravenous vs. Acetaminophen intravenous in neonates and young infants undergoing major non-cardiac surgery

Rationale: Hypotheses:

Patients after non-cardiac thoracic or abdominal major surgery 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 postoperative pain relief. Intermittent administration of intravenous acetaminophen, to young infants up to 48 hours after major surgery e.g. thoracic and abdominal, will lead to a clinically significant (>30%) morphine sparing effect.

Objective:
The aim of this study is to test the hypothesis that intravenous acetaminophen will reduce morphine requirements in postoperative infants significantly (>30%).

Study design:
Single centre prospective, randomized double blind study.

Study population:
Infants less than one year of age, who are admitted to the ICU after major thoracic (non-cardiac) or abdominal surgery.

Intervention:
Patients will be randomized to receive either intermittent intravenous acetaminophen or continuous morphine IV infusion up to 48 hrs after surgery, with additional morphine boluses as escape medication in both groups.

Main study parameters/endpoints:
Body weight corrected morphine dose needed in the first 48 hrs post surgery. Mean morphine dose needed will be 30% less in the infants receiving acetaminophen IV as compared to the patients who received only morphine

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Possible burden and risk of study participation is the risk of insufficient analgesia after surgery with acetaminophen IV. This risk is minimized by the provision in the protocol for the administration of additional morphine in case of insufficient analgesia.

Acetaminophen has been widely studied in children over all age ranges and is deemed safe in the population to be studied when administered in therapeutic doses.

Benefits of participation can be better observation of the patient in relation to his/her analgesia and more prompt response with additional morphine if necessary. Hence, we expect patients in the study to be more pain free than patients not participating in a pain trial.

Also, if acetaminophen indeed reduces the total morphine dose required, a reduction in adverse effects of morphine can be expected (less post operative vomiting, less respiratory depression).

The study can only be carried out in this population as results from adults or healthy children cannot be extrapolated to this group of patients (critically ill children), due to differences in age and the underlying disease, which are mainly life threatening congenital anomalies, resulting in differences in pharmacokinetics and pharmacodynamics of both drugs.

Doel van het onderzoek

Patients after non-cardiac thoracic or abdominal major surgery 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 postoperative pain relief. Intermittent administration of intravenous acetaminophen, to young infants up to 48 hours after major surgery e.g. thoracic and abdominal, will lead to a clinically significant (>30%) morphine sparing effect.

Onderzoeksopzet

Patients are followed 48 hours post operatively or is ended after an earlier discharge.

Onderzoeksproduct en/of interventie

After surgery patients will be randomised for treatment with Morphine or Acetaminophen intravenoously.

In case of post operative pain (COMFORT score>=17 and/or VAS>= 4) additional morphine in both groups is administrated following our post-operative pain protocol.

For PK-PD relationship for acetaminophen IV and morphine in this population three blood samples are taken from an indwelling arterial line and saliva cortisol is obtained.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent.

2. Neonate / child under the age of one year.

3. Minimal post conceptual age of 36 weeks.

4. Minimal body weight of 1500 grams.

5. Major thoracic (non cardiac) or abdominal surgery, including urological surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Withdrawal of informed consent.

2. Neonate/child with neurological, renal insufficiency, or hepatic dysfunction.

3. Chronic (more than one day) opioid or psychotropic drug (e.g. antiepileptics, benzodiazepines, antidepressants) exposure pre- or postnatal.

4. Opioid exposure <24 hrs before surgery.

5. Receiving ECMO-therapy.

6. Known allergy / intolerance for acetaminophen or morphine.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2008
Aantal proefpersonen:	72
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1378

Register	ID
NTR-old	NTR1438
Ander register	MAIV : MEC-2007-355
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A