Wound catheter infusion after abdominal surgery in baby's.

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This study investigates the hypothesis that regional anesthesia provided by wound catheter infusion (WCI) with ropivacaine reduces pain postoperatively (as measured with COMFORT behavior scale and NRS Pain scores) and leads to a morphine-sparing...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20504

Bron
Nationaal Trial Register

Aandoening

postoperative pain infants neonates abdominal surgery locoregional anesthesia ropivacaine wound catheter

Ondersteuning

Primaire sponsor: Erasmus MC-Sophia Children's Hospital
Rotterdam
the Netherlands
Overige ondersteuning: Coolsingel Foundation (Stichting Coolsingel)
Erasmus Foundation for Pain (Stichting Erasmus Fonds Pijngeneeskunde)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The mean cumulative amount of morphine administered over 48 hours postoperatively, in

mcg/kg, will be compared in both groups (R group and control group).

Toelichting onderzoek

Doel van het onderzoek

This study investigates the hypothesis that regional anesthesia provided by wound catheter infusion (WCI) with ropivacaine reduces pain postoperatively (as measured with COMFORT behavior scale and NRS Pain scores) and leads to a morphine-sparing effect of at least 30% after abdominal surgery in infants < 1 year of age.

Onderzoeksopzet

Children will receive a woundcatheter at the end of the operation, which will be removed after 72 hours postoperatively.
One week after the operation the parents will be contacted to fill out a questionnaire.

Onderzoeksproduct en/of interventie

At the end of abdominal surgery, following closure of the muscle layers and subcutaneous tissue, the surgeon will place a multi-hole wound catheter superficial to the muscle fascia under direct vision (On Q® Soaker Catheter, Halyard) and tunneled from a separate stab incision approximately 3 cm lateral to the wound.
Hereafter the skin is sutured. The catheter is fixated to the skin with a plaster (Steri Strip™ and Tegaderm™) and is connected to a syringe in a perfusor pump, which is filled with either ropivacaine 0.2% or saline (placebo). Before end of anesthesia, all children will receive a bolus dose via the wound catheter: ropivacaine 2 mg/kg (R group) or the same amount in ml/kg of saline (saline) in the control group. WCI is started postoperatively: ropivacaine 0.2 mg/kg/h (R group) or saline (control group) in the same amount.

At the end of surgery, the control group will receive a bolus dose of morphine 100 mcg/kg IV, because this is standard of care after major surgery in the Erasmus MC-Sophia (local pain protocol). Group R receives placebo (saline) in the same amount as IV bolus dose. All patients receive a first dose of paracetamol 20 mg/kg IV at the end of surgery. Paracetamol IV is continued on the PICU as standard analgesic, also according to local pain protocol.

Postoperatively, all children are admitted to the PICU. At the PICU, postoperative pain is assessed in all children using the COMFORT behavior scale and NRS pain. Based on these validated pain assessments, patients receive rescue morphine doses, when needed, according to an algorithm.

Children will be followed up for 72 hours postoperatively, after which the catheter will be removed.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Informed consent

- Children < 1 year of age

- Minimal post-conceptual age of 35 weeks

- Minimal body weight of 1500 grams

- Abdominal (open) surgery

- Admitted to the PICU postoperatively

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Withdrawal of informed consent

- Child with neurological disease, renal or hepatic dysfunction

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

- Opioid exposure <24 hrs before surgery

- Receiving ECMO therapy

- Known allergy / intolerance for paracetamol or morphine

- Contra-indications for regional analgesia techniques:

o Allergy to local anesthetics

o Local or general infection (sepsis)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2017

Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47384
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5949
NTR-old	NTR6130
EudraCT	2015-002209-12
CCMO	NL59689.078.17
OMON	NL-OMON47384

Resultaten