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...

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

Summary

ID

NL-OMON20504

Source
Nationaal Trial Register

Health condition

postoperative pain infants neonates abdominal surgery locoregional anesthesia ropivacaine wound catheter

Sponsors and support

Primary sponsor: Erasmus MC-Sophia Children's Hospital
Rotterdam
the Netherlands
Source(s) of monetary or material Support: Coolsingel Foundation (Stichting Coolsingel) Erasmus Foundation for Pain (Stichting Erasmus Fonds Pijngeneeskunde)

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Secondary Objectives:
1. Efficacy of treatment of postoperative pain: To determine if WCI with ropivacaine provides adequate treatment of postoperative pain, COMFORT behaviour scale and NRS Pain are measured, and these pain assessments are used to administer rescue morphine doses IV.
Parameters:
• Number of patients needing extra morphine boluses (rescue), over 48 hours.
• Total amount of morphine administered postoperatively, until removal of the wound catheter.
• AUC 24 hours COMFORT-B score and NRS, and percentage of high pain scores (NRS ≥ 4 and COMFORT ≥ 17).
2. Safety of the use of WCI with ropivacaine: To investigate if WCI with local anesthetics is safe for the treatment of postoperative pain in children, the incidence of adverse events related to the wound catheter and the use of ropivacaine is registered
Parameters:
• Toxicity due to overdose or inadvertent intravascular injection of local anesthetic:
- hypotension
- arrhythmia
- convulsions
• The incidence of adverse effects related to the wound catheter:
- accidental luxation of the wound catheter
- infection (wound infection, sepsis)
- hematoma of the wound
- delayed healing of the wound
- wound dehiscence
• Plasma concentrations of ropivacaine (total and unbound) will be measured during the phase of continuous infusion in the wound, to determine if plasma levels do not exceed toxic thresholds.
3. Adverse events related to the use of opioids:
• Signs of respiratory depression:
- number of apnea episodes
- number of intubated and ventilated patients in each group, when arriving on the PICU
- time on the ventilator postoperatively
- number of reintubated patients during the study period
- number of patients receiving naloxone
- time until discharge from the PICU
• Gastro-intestinal:
- signs of intestinal obstruction and nausea and vomiting
- time to first feeding
• Hemodynamic:
- hypotension with the need for vaso- active medication or fluid boluses
- bradycardia (other than due to or directly related to the disease or operation)
4. Other variables:

• Surgical stress:
To classify the surgical stress of the different procedures, the Surgical Stress Score is computed by the surgeon at the end of surgery: the amount of blood loss (score range 0-3); site of surgery (score range 0-2); amount of superficial trauma (score range 1-3); extent of visceral trauma (score range 1-4); duration of surgery (score range 1-5); associated stress factors: hypothermia (score range 0-3) and infection (score range 0-3). The total scores are used to divide the procedures in minor, moderate or severe surgical stress.
• The Parents' Postoperative Pain Measure- Short Form: One week after the operation, the parents are contacted to fill out a questionnaire: the PPPM-SF, a validated questionnaire, which shows the postoperative recovery of a child after discharge from the hospital.

Study description

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47384
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results