Epidural versus intravenous analgesia in children; a double-blind randomized controlled trial.

Gepubliceerd: 25-04-2006 Laatst bijgewerkt: 18-08-2022

To investigate whether epidural analgesia provides a better postoperative pain control than intravenous opioid analgesia in children and whether epidural analgesia is associated with reduced postoperative morbidity.

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

Samenvatting

ID

NL-OMON28626

Bron
NTR

Verkorte titel
EVIAN

Aandoening

elective upper/lower abdominal, urological or thoracic surgery

Ondersteuning

Primaire sponsor: D. Tibboel, MD, PhD
Head of Pediatric Surgical Intensive Care
Erasmus MC- Sophia Children's Hospital
Dr. Molewaterplein 60
3015 GJ Rotterdam
T +31 10 4636567
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Pain intensity;
2. Epidural/iv analgesics consumption;
3. Side effects.

Toelichting onderzoek

Achtergrond van het onderzoek

Systemic opioids and epidural analgesia are for major thoracic/abdominal surgery the two most common forms of postoperative analgesia both in adutls as in children. In adults epidural analgesia has beneficial effects on postoperative outcome and provides better pain control than intravenous opioids. In children however there is limited objective evidence that epidural analgesia after major surgery is more effective than intravenous opioid analgesia. Next to this it is unclear if the adverse effect profiles differ with both techniques. Aim of this study is to investigate whether epidural analgesia provides better postoperative pain control than intravenous analgesia in children and to find out whether epidural analgesia is associated with reduced postoperative morbidity.

Doel van het onderzoek

To investigate whether epidural analgesia provides a better postoperative pain control than intravenous opioid analgesia in children and whether epidural analgesia is associated with reduced postoperative morbidity.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patient controlled intravenous analgesia versus patient controlled epidural analgesia.

Contactpersonen

Publiek

Erasmus Medical Center
Sophia Children’s Hospital
Department of Pediatric Surgical Intensive Care

D. Tibboel
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636567

Wetenschappelijk

Erasmus Medical Center
Sophia Children’s Hospital
Department of Pediatric Surgical Intensive Care

D. Tibboel
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636567

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 6-18 years;

2. ASA I or II.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Preoperative use of analgesics/opioids(chronic) pain syndromes;

2. Endocrine and neurological disorders;

3. Psychiatric disorders;

4. Peripheral neuropathy;

5. Mental retardation;

6. Medication influencing somatosensory function;

7. Indifference/insensitivity to pain;

8. Contraindications to epidural analgesia;

9. Contraindications to self-administration of opioids.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-05-2006
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-04-2006
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	NL605
NTR-old	NTR662
Ander register	: N/A
ISRCTN	ISRCTN94873343

Resultaten

Samenvatting resultaten
N/A