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

No registrations found.

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

Summary

ID

NL-OMON28626

Source NTR

Brief title EVIAN

Health condition

elective upper/lower abdominal, urological or thoracic surgery

Sponsors and support

Primary sponsor: D. Tibboel, MD, PhD
Head of Pediatric Surgical Intensive Care
Erasmus MC- Sophia Children's Hospital
Dr. Molewaterplein 60
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Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary hyperalgesia.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

Patient controlled intravenous analgesia versus patient controlled epidural analgesia.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. 6-18 years;
- 2. ASA I or II.

Exclusion criteria

- 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.

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):	08-05-2006
Enrollment:	60
Туре:	Actual

Ethics review

Positive opinion	
Date:	25-04-2006
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	NL605
NTR-old	NTR662
Other	: N/A
ISRCTN	ISRCTN94873343

Study results

Summary results

N/A