

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

Submission date 07/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 07/06/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 07/06/2006	Condition category Surgery	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

EVIAN

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double-blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain during thoracic and abdominal surgery

Interventions

Patient controlled intravenous analgesia versus patient controlled epidural analgesia

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Secondary hyperalgesia

Completion date

08/11/2006

Eligibility

Key inclusion criteria

1. 6-18 years
2. American Society of Anesthesiologists (ASA) I or II

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Preoperative use of analgesics or opioids for (chronic) pain syndromes
2. Endocrine and neurological disorders
3. Psychiatric disorders
4. Peripheral neuropathy
5. Mental retardation
6. Medication influencing somatosensory function
7. Indifference or insensitivity to pain
8. Contraindications to epidural analgesia
9. Contraindications to self-administration of opioids

Date of first enrolment

08/05/2006

Date of final enrolment

08/11/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation

Erasmus Medical Center, Department of Anesthesiology (The Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

University/education

Funder Name

Erasmus Medical Center

Alternative Name(s)

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

