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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Secondary hyperalgesia

Overall study start date
08/05/2006

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

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
P.O. Box 2040
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3000 CA

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration