ISRCTN94873343 https://doi.org/10.1186/ISRCTN94873343

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

Contact name
Prof D. Tibboel

Contact details
Erasmus Medical Center
Sophia Children's Hospital
Department of Pediatric Surgical Intensive Care
Dr. Molewaterplein 60
Rotterdam
Netherlands
3015 GJ
+31 (0)10 4636567
j.illsley@erasmusmc.nl

Additional identifiers

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

Primary study design
Interventional

Study design
Double-blind randomized controlled trial

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