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Peri-operative pain management in children and adolescents undergoing scoliosis surgery: pain, nausea and psychological impact

Submission date 20/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/07/2009	**Overall study status** Completed	
Last Edited 17/01/2020	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-001642-19

Protocol serial number
EudraCT:

Study information

Scientific Title
Intravenous analgesia with S-ketamine and morphine versus epidural analgesia with fentanyl, bupivacaine and epinephrine: a randomised controlled trial

Acronym
SPIC

Study objectives
Patient-controlled intravenous analgesia with morphine and S-ketamine hydrochloride is as effective in pain control with less invasiveness and has comparable or less adverse effects as patient-controlled epidural analgesia with bupivacaine, fentanyl and epinephrine after scoliosis surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Board of Umea University, Sweden gave approval on 5th December 2008 (ref: 08-056)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-operative pain after scoliosis surgery

Interventions
In one arm pain treatment consist of a continued epidural infusion of a mixture of bupivacine 1 mg/ml, epinephrine 2 µg/ml and fentanyl 2 µg/ml with patient controlled extra boluses of 0.1 ml /kg to a maximum 5 ml. Initial bolus will be 0.02 ml/kg/segment (maximum of 15 ml) and an initial infusion rate of 0.2 ml/kg/h (maximum of 15 ml/h). Maximal infusion rate inclusive bolus doses will not exceed 0.4 ml/kg/h. The epidural infusion rate is adjusted according to effect and spread.

In the other arm pain treatment consists of a continues intravenous infusion of (S)-ketaminehydrochlorid 1 mg/ml 0.1 mg/kg/h and will be started after an initial bolus of 0.25 mg /kg. Morphine 1 mg/ml administered as a Patient Controlled bolus intravenous injection of 25 µg /kg lock out time 6 minutes, after an initial repeated boluses of 50 µg/kg until pain is lower than 30 mm measured with Visual Analogue Scale (VAS) (0 - 100 mm). A continuous infusion of morphine will be started at a rate of 10 µg/kg/h. The bolus dose or the infusion rate will be adjusted according to needs. Background infusion may be increased 5 µg/kg/h until a maximum of 25 µg/kg/h.

These treatments will be given for 6 days. Follow up of pain, side effects, bowel function and mobilisation will be as long as the patient is hospitalised (about 9 days) and further 2 weeks at home.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine, S-ketamine hydrochloride, bupivacaine, fentanyl, epinephrine

Primary outcome(s)
Patients self-report on pain at rest, measured with a Visual Analogue Scale (VAS) (0 - 100 mm, where 0 means no pain and 100 means worst possible pain) every 4 hours during the six first post-operative days.

Key secondary outcome(s))
1. Pain in motion (during coughing) measured once every 24 hours, VAS (0 - 100 mm)
2. Nausea: defined as 0 = no nausea, 1 = a little nausea, 2 = much nausea, and 3 = vomiting will be monitored every 4 hours and when the patient reports nausea
3. Pruritus defined as: 0 = no pruritus, 1 = pruritus will be monitored when occurring
4. Bowel activity: measured every 12 hours and defined as follows: bowel sounds = 1, first flatus = 2, first tolerated meal = 3, first bowel movement (defined by the patient as defecation) = 4
5. Time to first demanded dose
6. Time to first rescue-analgesia measured from the start of the post-operative study-protocol. Criteria for rescue-administration will be pain, self-report VAS greater than 30 mm in spite of the study protocol for pain management in the respective PCIA and PCEDA groups.
7. Number of demanded PCA-doses
8. Number of rescue doses
9. Total amount of rescue-morphine measured in mg
10. Occurrence of negative psychological effects, as nightmares, hallucinations or confusion
11. A rating of the participants global satisfaction, rated once a day (very satisfied = 0, satisfied = 1, dissatisfied = 2, very dissatisfied = 3)
12. Adherence to mobilisation plan will be recorded daily (0 = plan not fulfilled, 1 = plan fulfilled, 2 = ahead of plan)
13. Length of stay in the hospital (LOS) measured from the day of surgery

Outcome-measures in the follow up study will be:
1. The Trauma Symptom Checklist for Children and the adolescents completed at 1 month after returning home
2. Self-reports of common pain and worst pain, will be rated every day, the first 14 days at home after the surgery
3. The adolescents will write a diary on how they experience the first 14 days at home
4. Interviews will be performed 1 month after the surgery

Completion date
01/04/2011

Eligibility

Key inclusion criteria
Children and adolescents (aged 12 - 18 years, either sex) with idiopathic scoliosis scheduled for correction by posterior spinal fusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Pregnant
2. Allergic to study drugs
3. Unable to present self reports on pain and nausea

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Anesthesia
Umeå
Sweden
SE 90185

Sponsor information

Organisation
University Hospital of Northern Sweden (University Hospital of Umeå)

ROR
https://ror.org/012k96e85

Funder(s)

Funder type
Government

Funder Name
Västerbotten Läns Landsting

Alternative Name(s)
Västerbotten County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration