

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/01/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

**Protocol serial number**  
EudraCT: 2008-001642-19

## 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 bupivacaine 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