PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

THE INFLUENCE OF EPIDURAL ANALGESIA VERSUS PATIENT-CONTROLED INTRAVENOUS ANALGESIA ON THE STRESS RESPONSE AFTER MAJOR SPINE SURGERY
(A randomized double blind study)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In our study we studied postoperative pain management after major spine surgery.The patients were divided in two groups after they choosed sealed envelope in which the group was written. Only the nurse who prepared drugs knew in which group belongs the patient.
All patients received i.v. therapy with opioid piritramide with PCA (that means that the patients near basal level of opioid infusion could administer another dose of opioid themselves if they needed it). The patients in first group got local anaesthetic levobupivacaine administered via epidural catheter which was inserted on the end of the surgery in epidural place near spinal cord. The second group received 0,9% NaCl via epidural catheter. We measured the level of pain and stress response in both groups of patients.

Brief Summary in Scientific Language

Abstract: CONTEXT: We hypothesised that the postoperative epidural analgesia after lumbar spinal
fusion provides better analgesia and lowers the postoperative stress.
OBJECTIVES: This study compared epidural postoperative analgesia with PCA-piritramide after the
spinal fusion. We compared the postoperative pain level and stress response.
DESIGN AND SETTINGS: This a prospective randomised and double blind study. It was performed in
tertiary care centre.
PATIENTS: In the study were included 81 patients who undergone spinal fusion in the time between end of the
June 2007 and November 2010.The patients were allocated in two groups.
Exclusion criteria: mental illness, drug addiction, renal or hepatic insufficiency, spondilodiscitis,
known local anaesthetic allergy.

**In the time of study 13 patients were excluded because of epidural catheter displacement, patient's
confusion, consent withdrawal and postoperative corticosteroid treatment.
INTERVENTION: After spinal fusion the epidural catheter was inserted.
MAIN OUTCOME MEASURES: We measured VAS, analgesic consumption, blood glucose, cholesterol
and cortisol level, postoperative bleeding, peristalsis , time of first postoperative defecation and
hospital stay.**

Organizational Data

- DRKS-ID: **DRKS00003192**
- Date of Registration in DRKS: **2011/07/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **135/06/07 , Slovene national medical ethics comity Institut za klinicno nevrofiziologijo, UKC Ljubljana**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1122-1213**

Health condition or Problem studied

- ICD10: **M43.1 - Spondylolisthesis**
- Free text: **SPINALFUSION and postoperative pain**

Interventions/Observational Groups

- Arm 1: **Levobupivacaine via epidural catheter: after the epidural catheter insertion the patients got 0,125% levobupivacaine in the dosage after Bromage and then 0,125% lev0bupivacaine 0,1ml/kg /h for 72 hours. They got also piritranide i.v. via PCA (patient controlled analgesia) pump with basal infusion 1mg/h and bolus 2,5 mg with lock out time 30 minutes for 24 hours. After that they got Metamisole or Piritramide bolus i.v. if needed.**
- Arm 2: **piritramide i.v. via PCA:They got piritramide i.v. via PCA (patient controlled analgesia) pump with basal infusion 1mg/h and bolus 2,5 mg with lock out time 30 minutes for 24 hours. After that they got Metamisole or Piritramide bolus i.v. if needed.
In this group received patients via epidural catheter 0,9% NaCl (0,1ml/kg in bolus after the catheter insertion and later in dosage after Bromage).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

**VAS (visuel analog scale) pain score each 6hours for 5 days,
analgesics consuption in summary for 5 days, cortisol, blood glucose and cholesterol level before surgery and for 4 postoperative days each day,
days day of hospital stay**

Secondary Outcome

**peristalsis after 24 hours,
side effects,
postoperative bleeding,
time to first postoperative defecation**

Countries of recruitment

- SI **Slovenia**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/06/20**
- Target Sample Size: **81**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2007/06/20**

Target Sample Size: **81**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

patients between 30-80 years
ASA 1-3
spondylolystesis with spinal fusion and instrumentation

Exclusion criteria

mental illness
drug addiction
renal or hepatic insufficiency
spondylodiscitis
neurological deficits
known allergy to local anesthetics

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Institutional budget , no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/11/30**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*