

Epidural compared to General Anesthesia for Lumbar Spine Surgery

Published: 23-07-2007

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To assess whether there is less peri-operative pain and a faster post operative recovery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON30574

Source

ToetsingOnline

Brief title

Epidural General lumbar Surgery

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym

Lumbar Herniated Disc, Lumbar Herniated Nucleus Pulposus

Research involving

Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis

Source(s) of monetary or material Support: Sint Lucas Andreas Ziekenhuis

Intervention

Keyword: Anesthesia, Epidural, Lumbar spine, Surgery

Outcome measures

Primary outcome

- 1 complications from positioning the patient
- 2 feed back from the patient during surgery
- 3 peroperative bloodloss
- 4 postoperative pain
- 5 postoperative nausea and vomiting
- 6 urine retention
- 7 patient satisfaction
- 8 duration of surgery

Secondary outcome

post operative recovery

Study description

Background summary

Lumbar spinal cord surgery can be performed safely under general anesthesia (GA) or epidural anesthesia (EA). GA is mostly preferred because of greater patient and physician acceptance and the ability to perform operations of longer duration in the prone position with a secured airway. It is demonstrated that regional anesthesia reduces blood loss (1). During EA the awake patient can self-position to avoid nerve injury of the brachial plexus and pressure necrosis especially to the face. In addition, the perioperative feed-back of the patient allows precise localisation of the involved nerve root to the surgeon and guarding against injuries. Finally, this technique provides excellent long lasting postoperative analgesia. Proposed disadvantages of EA for this surgery are the inability to immediately assess the neurological function, and affected bladder function.

The Sint Lucas Andreas Hospital has performed EA for lumbar spine surgery successfully since the early eighties. Although the broad experience this has never been evaluated for perioperative blood loss, time of discharge from the recovery unit and the common postoperative problems such as pain, analgesic

need, nausea, and vomiting.

Greenbarg et al. Epidural anesthesia for lumbar spine surgery. J Spinal Disord. 1988;1(2):139-43

Study objective

To assess whether there is less peri-operative pain and a faster post operative recovery.

Study design

We designed a prospective randomised trail to compare GA and EA for lumbar spinal cord surgery.

Intervention

Either general anesthesia (control group) or epidural anesthesia (study group).

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with the age from 18 years old, who will undergo lumbar spine surgery.

Exclusion criteria

Severely cardio-pulmonal compromised patients will be excluded from this study.
(ASA=3 or ASA>3)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2006
Enrollment:	200

Type:

Anticipated

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14194.029.06