Epidural anesthesia compaired to general anesthesia for lumbal spinal surgery (Voordeurstudie study).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23416

Source
NTR

Brief title
De Voordeurstudie

Intervention

Outcome measures

Primary outcome

Pain perception post OK using the visual analog scale (VAS).

Secondary outcome

1. Blood loss;

2. Blood pressure variations;

3. Feed back from the patients recovery time;

4. Postoperative nausia and vomiting;

5. Urine retention;

6. Patient satisfaction.

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 safe 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 eighteis. 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.

Study objective

Epidural anesthesia is superiour to general anesthesia considering pain control, blood loss, urine retention, recovery duration and general well being for the patient.

Study design

N/A

Intervention

1. Study group: epidural anesthesia;

2. Control group: general anesthesia.

Contacts

Public
M.B. Godfried
[default]
The Netherlands
Scientific
M.B. Godfried
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Patients from 18 years old who are ASA<3.

Exclusion criteria

ASA 3-5 patients and those who received lower back surgery twice or more.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	05-12-2006
Application type:	First submission

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
NTR-new	NL835
NTR-old	NTR848
Other	: N/A
ISRCTN	Incomplete info for ISRCTN

Study results

Summary results
N/A