a Randomized controlled trial for epidural Analgesia for Pain relief after lumbar Interlaminar Decompressive spine surgery.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25260

Source
NTR

Brief title
RAPID

Health condition

Lumbar spinal stenosis

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Difference in NRS

Secondary outcome

Opiod use,hospital stay, adverse events, patient satisfaction

Study description

Background summary

The objective of this study is to determine whether intraoperative epidural analgesia (bupivacaine/sufentanil) is superior to placebo in reducing wound pain in patients after decompressive lumbar spine surgery, and to determine whether opioid use in the 2 days after surgery is significantly higher in the placebo group.

Study objective

Epidural analgesia is superior to placebo in reducing post-operative pain.

Study design

First 48 hours post operative

Intervention

Epidural analgesia; Bolus 10ml of bupivacaine 0,125%-sufentanil 1 mcg/ml
Placebo 10ml of NaCl 0,9%

Contacts

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Eligibility criteria

Inclusion criteria

- Indication for open interlaminar decompressive lumbar spine surgery.
- Age over 18 years.
- Psychosocially, mentally, and physically able to fully comply with this study protocol.
- Informed consent prior to this study.

Exclusion criteria

- Pre-operative opioid use (approximately 40% of patients)
- Previous radiotherapy at the intended surgical level.
- (Progressive) motor failure and/or anal sphincter disorders which urges instant intervention.
- Active spinal infection.
- Immature bone (ongoing growth).
- Pregnancy.
- Contra-indications for anesthesia or surgery.
- Inadequate command of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	34
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49530
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8030
CCMO	NL71390.096.19
OMON	NL-OMON49530

Study results