Research into the effect of local anesthetic as additional pain relief after surgery on the lower back

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26038

Source
Nationaal Trial Register

Brief title
RCT-ESPB

Health condition

Spondylolisthesis, lumbar disc herniation

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Pain intensity in the postoperative care unit upon emergence, using the Numeric Rating Scale (NRS) for pain

Secondary outcome

- Acceptability of pain;
- Opioid use in cumulative morphine equivalent dose (MEQ) in the postoperative care unit and in the first 24 hours after surgery;
- Opioid side effects such as nausea, vomiting and use of anti-emetics in the postoperative care unit and in the first 24 hours after surgery;
- Time to first opioid use/request;
- Time to first mobilization;
- Length of hospital stay;
- Pain intensity on postoperative admission days, before discharge from hospital, and after 30 days;
- Opioid use 30 days after surgery;
- Quality of recovery on postoperative day 1 and before discharge;
- Complications up to 30 days postoperative.

Study description

Background summary

Rationale: Lumbar spine surgery is associated with high postoperative pain scores and analgesic use, despite use of multimodal analgesia. The erector spinae plane block (ESPB) is a promising locoregional anesthetic technique for this type of surgery. The literature is not yet conclusive about the effectiveness of this technique on reducing postoperative pain intensity.

Objective: The objective of this study is to evaluate the analgesic effect of ESPB as add-on therapy to multimodal analgesia on early postoperative pain intensity after lumbar spinal fusion surgery compared to placebo.

Study design: The study is designed as a prospective mono-centre, randomized, double-blinded, placebo-controlled trial.

Study population: 76 patients ≥ 18 years of age requiring elective lumbar spinal fusion surgery involving two to four fusion levels.

Intervention: Patients will receive ultrasound-guided ESPB with either ropivacaine or placebo at the end of surgery.

Main study parameters/endpoints: Main study parameter is pain intensity upon emergence from anesthesia measured with the Numeric Rating Scale. A minimal clinically important difference is considered to be a decrease of 1.5 points. Secondary endpoints are pain intensity during hospital stay and after 30 days, opioid use during hospital stay and after 30 days, opioid side effects, use of anti-emetics, time to first opioid use/request, length of

hospital stay, quality of recovery at discharge.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The Sint Maartenskliniek is experienced in applying locoregional analgesia, the use of ropivacaine and using sonography. The procedure of administering ESPB has a very low risk of complications. Receiving placebo is justifiable because this group will not be withhold standard treatment. The risks of receiving placebo are negligible. The patients will visit the clinic at regular follow-up moments.

Study objective

The null hypothesis states there is no difference in effectiveness of the ESPB compared to placebo on early postoperative pain intensity measured with NRS in patients that underwent lumbar spine fusion surgery.

Study design

Preoperative, day of surgery, PACU-admission, postoperative day 1 until discharge, 30 days postoperative

Intervention

Erector Spinae Plane Block injection with ropivacaine

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 years;
• Patients planned for elective lumbar spinal fusion surgery with a dorsal surgical approach;
• 2-4 level spine fusion surgery;
• Written informed consent.

Exclusion criteria

• A Body Mass Index (BMI) > 40 kg/m^2;
• ASA physical health classification > 3;
• Patients who will undergo spine surgery involving less than 2 or more than 4 levels of fusion, scoliosis surgery;
• Patients who will undergo circumferent spine surgery;
• Patients with an active, local infection or systemic infection;
• Patients with an allergy to one or more medications used in the study;
• Patients with any contraindication to a regional anesthetic technique;
• Kidney- or liver failure inhibiting the systemic use of paracetamol and/or NSAIDs;
• Acute surgeries;
• Patients with a history of drugs or alcohol abuse;
• Pregnancy;
• Cognitive impairment;
• Inability to speak or understand 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:	Recruiting
Start date (anticipated):	01-02-2022
Enrollment:	76
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-08-2021
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	NL9640
Other	Commissie Mensgebonden Onderzoek regio Arnhem-Nijmegen : CMO regio A-N 091

Study results