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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26038

Bron
NTR

Verkorte titel
RCT-ESPB

Aandoening

Spondylolisthesis, lumbar disc herniation

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Erector Spinae Plane Block injection with ropivacaine

Contactpersonen

Publiek

Sint Maartenskliniek
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• A Body Mass Index (BMI) > 40 kg/m²;

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2022
Aantal proefpersonen:	76
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9640
Ander register	Commissie Mensgebonden Onderzoek regio Arnhem-Nijmegen : CMO regio A-N 091

Resultaten