Erector spinae plane block for post-operative analgesia management following video-assisted thoracoscopic surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49968

Source
ToetsingOnline

Brief title
Erector spinae plane block following VATS

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
post-operative pain

Health condition

post-opereratieve pijn

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: R&D anesthesiologie

Intervention

Keyword: ESBP, lungsurgery, post-operative analgesia, VATS

Outcome measures

Primary outcome

The postoperative pain assessment is performed using NRS score (0 = no pain, 10 = most severe pain felt). Pain score at rest, while coughing and during mobilisation will be recorded at 0, 2, 4, 8, 12 and 24hours postoperatively and at day 2, two times a day at 08:00 and 20:00. Measured by a nurse who is trained to take NRS scores.

Secondary outcome

• Total opioid consumption in milligrams after 24 hours and 48 hours.

• Length of stay at the recovery unit in minutes

• Patient satisfaction (NRS 0-10)

• Hospital length of stay in days

• Nausea, vomiting (yes / no) day 0 and 1 post-operatively requested in the evening.

• Adverse events (pneumonia: diagnosed with a chest x-ray and positive sputum culture)

Study description

Background summary

Post-operative pain management after minimal invasive video-assisted thoracoscopic surgery (VATS) is previously managed with invasive techniques as thoracic epidural anesthesia or paravertebral block. These techniques have rare but serious risks. The less invasive intercostal block is often insufficient and oral and parenteral opiods are frequently used. Opiates give side effects such as nausea and sedation. The erector spinae plane block (ESPB) is an alternative for the invasive pain management techniques and recudes opioid consumption with fewer side effects.
In 2016 Forero et al. first described the ESPB, an interfascial plan block. This novel regional anesthesia technique can be used for postoperative pain management of the thoracoabdominal region. Recent emerging research showed ESPB as a simple and safe analgesic technique for postoperative thoracic pain. The ESPB is only described in case series in patients who have undergone a VATS lobectomy or wedge excision, no adverse events such as hypotension, hematoma or infection are mentioned.

Study objective

This study aims to test the hypothesis that ultrasound guided ESPB compared to patient controlled analgesia with Morphine, after a VATS lobectomy of wedge excision, reduces acute post-operative pain and opioid consumption. Our secondary aims are to examine patient satisfaction, nausea and length of stay at the recovery unit and hospitalization.

Study design

This study is a double blind, prospectively randomized, placebo controlled study. The patients are divided in two groups. After routine monitoring, general anesthesia was induced in both groups. After induction an ultrasound guided erector spinea plane block will be performed. Once the needle tip is placed whitin the interfacial plane below the erector spinae muscle 20cc Levobupivacaine 0,5% will be injected in group 1 en 20cc NaCl 0,9% in group 2. Paracetamol, Diclofenac and 0,1mg/kg Morphine is administered in both groups after induction.
For postoperative analgesia, a 1000mg dose of Paracetamol every 6 hours and 50mg Diclofenac every 8 hours will be administered. All patients received as rescue medication Morphine via a patient controlled analgesia device for the first 24 hours.
The postoperative pain assessment is performed using NRS score (0 = no pain, 10 = most severe pain felt). Pain score at rest, while coughing and during mobilisation will be recorded at 0, 2, 4, 8, 12 and 24hours postoperatively and

at day 2, two times a day at 08:00 and 20:00.
The postoperative opioid consumption side effects, such nauseau, vomiting and sedation were also recorded.

Intervention

After induction an ultrasound guided erector spinea plane block at the T5 vertebra level will be performed. Once the 22 gauge 50mm needle tip is placed whitin the interfacial plane below the erector spinae muscle 20cc Levobupivacaine 0,5% will be injected in group 1 en 20cc NaCl 0,9% in group 2. The anesthesiologist permorming the ESPB does not know whether Levobupivacaine or NaCl is injected.

Levobupivacaine, the pure S (*) enantiomer of bupivacaine, emerged as a safer alternative for regional anaesthesia than its racemic parent, with less affinity and depressant effects on myocardial and central nervous vital centres and a superior pharmacokinetic profile.

Study burden and risks

For the study the patient does not have to come to the hospital extra and there will be no additional medical examination. We ask the patient after surgery to enter the NRS pain score in the study diary and to indicate whether they are nauseous and how satisfied they are with the pain relief. The side effects of the local anesthetic, Levobupivacaine, are metallic taste, dizziness or confusion. With our dosage we remain below the toxic dosage

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 undergoing wedge resection or lobectomy through VATS

Exclusion criteria

contraindications for ESPB

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2020

Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL70485.100.19