Erector Spinae Plane Block versus Thoracic Epidural Block in Elective Video-Assisted Thoracic Surgery (VATS): A Prospective Randomized Open Label non-inferiority Trial

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Evaluate the non-inferiority of the ESP-block compared to the TEA in VATS lobectomy or wedge resection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48927

Source
ToetsingOnline

Brief title
ESP vs TEA for VATS

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
Postoperative pain treatment, Regional analgesia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Onderzoeksfonds

Intervention

Keyword: Erector Spinae Plane Block, Regional Anaesthesia, Thoracic Epidural Analgesia, VATS surgery

Outcome measures

Primary outcome

The primary outcome of this study is the QoR15 on POD 0,1 and 2

Secondary outcome

Secondary endpoints are Visual Analog Scales (VAS) score on POD 0,1 and 2 (assessed at rest and when moving (coughing) in the morning and in the evening), Length of hospital stay (LOS), failure of analgesic technique (defined as catheter failure, need for specialist intervention and/ or need for rescue medication), the postoperative morphine-equivalent consumption on POD 0,1 and 2, itching, nausea and vomiting, the total operative time (recorded as total time spent in the operating room, anesthetic time, surgical time), complications related to surgery (e.g. conversion to open procedure), perioperative hypotension (requiring prolonged use of vasopressors) complications related to pain treatment (e.g. epidural hematoma or local anesthetic toxicity) duration of bladder catheterization, first mobilization (to chair and > 20 meters)

Study description

Background summary

Regional anesthesia numbs only the area of the body that requires surgery by injecting local anesthetic near a cluster of nerves. It is added to the general anesthesia regimen to obtain improved pain relief during and after surgery. For video assisted thoracoscopic surgery (VATS), a thoracic epidural (TEA) is used in the Catharina Hospital Eindhoven and Maasstad Hospital Rotterdam as regional anesthesia technique. A thoracic epidural block interrupts the sensation by injecting local anesthetics near the spinal canal. Recently, the Erector Spinae Plane (ESP) block has been introduced by Forero and colleagues as a practical alternative to the thoracic epidural block. It interrupts the sensation by injecting local anesthetics in between the muscular layers of the thoracic wall and has been successfully reported as regional anesthesia technique for VATS surgery in case series. Injecting local anesthetic in between muscular layers is easier and safer than near the spinal canal.

Study objective

Evaluate the non-inferiority of the ESP-block compared to the TEA in VATS lobectomy or wedge resection.

Study design

This is an investigator-initiated prospective randomized open label non-inferiority trial comparing the TEA with ESP as regional anesthesia technique for VATS-surgery. The study will be performed in accordance with the Declaration of Helsinki (Fortaleza, Brazil, October 2013). A total of 90 patients are being randomly allocated to ESP(study group) or TEA (control group). This study is set up as a non-inferiority trial as we do not debate the analgesic effectiveness of a good working TEA. Furthermore, superiority is not considered necessary because of the previously mentioned advantages of ESP. It is not possible to create a double-blinded study protocol given these two visually different regional pain treatment modalities hence the open-label study design.
Patients will be followed until 48 hours after surgery or until discharge from the hospital.

Intervention

- Intervention arm: ESP

The ESP-block will be placed as described by Chin et al. First, the patient will be installed in the lateral or sitting position. A curve array probe or a high frequency linear probe, depending on the BMI of the patient, will be placed in a longitudinal position 2-3 cm lateral of the vertebral column. The transverse processes of T5, the erector spinae muscle and the psoas muscle are

identified. An epidural needle will be inserted with an in plane technique in a cephalad to caudad direction until bone contact with the top of the transverse process is reached. After slight retraction of the needle, hydrodissection with normal saline will allow to visualize the correct plane for injection. Then ropivacaine will. be injected followed by the insertion of the catheter 5cm beyond the needle tip. Patients over 70kg will receive 200mg ropivacaine (40ml), patients 50_70kg will receive 150mg ropivacaine (40ml) and patients under 50kg will receive ropivacaine 3mg/kg (40ml). During surgery, the catheter is not used. At the end of the surgery, 10ml op bupivacaine 0.125% will be injected through the catheter followed by a continuous infusion of 5ml bupivacaine 0.125%/hour and bolus option of 10ml bupivacaine 0.125% every 3 hours. When ESB does not provide adequate pain relief, minor adjustments or a manual top-up are allowed.

- Control arm: TEA
Preoperatively, an anesthesiologist places an epidural catheter between the T5-T7 level at the discretion of the anesthesiologist. The epidural catheter is managed following in house protocol. When CEA does not provide adequate pain relief, minor adjustments or a manual top-up are allowed.

Study burden and risks

* Both the study and the control group will receive a regional anesthesia technique using local anesthetics. The potential risks of a regional anesthesia technique are:
-Discomfort during puncture
-Allergy for the desinfectant or levobupivacaine
-Infection at the skin, needle trajectory or point of injection. The clinical presentation can be variable, like redness or in extreme cases an intramuscular abscess.
-Bleeding at the skin, needle trajectory or point of injection.
-Neural damage: The risk of neural damage is higher for the control group as the needle puncture is close to the spinal canal and nerve roots. For patients in the study group risk of neural damage is rare since the target of the puncture is a muscular plane and not the nerve root or nerve ramus itself.
-Local anesthetic systemic toxicity (LAST): A substantial amount of local anesthetic is used in the study group. This may results in a higher risk for LAST as is with any existing plane block. LAST can immediately be treated with intralipid.

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

(1) Age between 18 and 75 years,
(2) BMI between 18 and 30kg/m2,
(3) scheduled for elective VATS surgery, and
(4) written informed consent.

Exclusion criteria

(1) ASA status***4
(2) chronic opioid use (> 3 months of strong opioids, weak opioids such as tramadol are allowed)
(3) renal or liver failure inhibiting the systematic use of paracetamol and/or NSAIDs
(4) contraindication for epidural analgesia (e.g. INR or platelets according to local protocol, local infection at the surgery site or puncture site)
(5) allergy to study medication

(6) pregnancy
(7) cognitive impairment
(8) insufficient comprehension of the Dutch QoR-15 questionnaire.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2020
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	13-02-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	29-06-2020
Application type:	Amendment
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

ID: 22453
Source: NTR
Title:

In other registers

Register	ID
Other	Nederlands Trial register nr NL6433
CCMO	NL65158.100.18
OMON	NL-OMON22453