Optimal postoperative Pain management After Lung surgery

No registrations found.

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

Summary

ID

NL-OMON21054

Source
NTR

Brief title
OPtriAL

Health condition

Lung tumor

Sponsors and support

Primary sponsor: ZonMw, Maxima MC
Source(s) of monetary or material Support: ZonMw grant, Maxima MC

Intervention

Outcome measures

Primary outcome

The NRS (0-10; 0= no pain, 10=worst imaginable pain) will be used to measure pain scores. The primary outcome measure for ‘non-inferiority’ is the proportion of NRS ≥4, defined as the number of NRS ≥4 episodes divided by the total amount of NRS pain scores obtained. A minimum of 11 NRS pain scores will be collected (at the recovery room (1), on the ward (10)). The primary outcome for ‘superiority’ is QoR measured with the QoR-15 questionnaire on

POD 1 and POD 2. The QoR-15 will provide a continuous variable with a minimum score of 0 and maximum score of 150, and contains the most relevant questions concerning 5 domains (emotional status, physical comfort, psychological support, physical independence and pain) of overall well-being and recovery after surgery.

Secondary outcome

1) Pain scores during rest and mobilisation at baseline, in the morning, afternoon and evening on POD 0-3 and at 2-3 weeks follow-up;
2) Proportion of postoperative pain scores of NRS ≥4 during mobilization at POD 0-3;
3) QoR-15 pre-operatively (baseline), POD 0, POD 3 and at 2-3 weeks follow-up;
4) Cumulative use of systemic opioids and analgesics at POD 0-3;
5) Postoperative complications until 2-3 weeks follow-up, according to the Clavien-Dindo classification;
6) Hospitalization, defined as the total number of days in hospital after the surgical intervention (including readmissions within the first 30 postoperative days). The following standardised discharge criteria after surgery will be applied in all participating hospitals: normal intake of nutrition; independent mobility; absence of fever (<38 °C); and no presence of chest tube.
7) Patient satisfaction (5-point Likert scale: not at all satisfied, slightly satisfied, neutral, very satisfied and extremely satisfied);
8) Time to removal of thorax drain in days;
9) Time to removal of urinary catheter in days;
10) Degree of mobility (1-4 scale: on the bed (1), to the chair (2), to the toilet (3), outside the patient's hospital room(4));
NL75375.041.20 | OPtriAL | C1. Onderzoeksprotocol versie 2 dd 25-01-2021
11) Cost-effectiveness of analgesic techniques from a health care perspective (see paragraph 10.3.1 'Economic Evaluation');

Study description

Background summary

Rationale: Adequate pain control after video-assisted thoracic surgery (VATS) for lung resection is important to improve postoperative mobilisation and recovery, and to prevent postoperative pulmonary complications. Thoracic epidural analgesia (TEA) is the usual care for postoperative pain management following thoracic surgery. Although the analgesic effect of TEA is clear, failure rates are 9-30% and awake placement is stressful for patients. In addition, TEA is associated with patient immobilisation, bladder dysfunction and hypotension. Based on the best available evidence and the recent guidelines by the Enhanced Recovery After Surgery (ERAS) society, the European Society of Thoracic Surgeons (ESTS) includes early mobilisation after surgery as one of their key recommendations.

The disadvantages of the TEA initiated the development of unilateral regional techniques for

pain management. Single-shot and continuous paravertebral, intercostal, serratus anterior and erector spinae blocks have shown to be safe and effective. So far, no consensus exists on optimal postoperative pain management after VATS lung resection. The Dutch guideline database and the ESTS guideline on ERATS all address TEA as well as other regional techniques to be valid options for pain control after VATS.

In addition to studying pain, patient satisfaction and postoperative quality of recovery (QoR) are crucial factors in the decision making of patient selected analgesic techniques. Pain assessment continues to be a challenge due to its subjective nature and relation to various outcomes related to QoR, therefore, anaesthesia and pain studies strongly recommend using a patient related outcome measure reporting QoR to assess postoperative pain [14, 15].

Objective: The main objective is to compare regional continuous paravertebral block (PVB), single shot multi-level intercostal nerve block (ICNB) and thoracic epidural analgesia (TEA) as pain relief techniques in order to provide safe, effective and efficient pain management after thoracoscopic lung surgery. This study will provide the evidence for an ERATS protocol to be implemented for the optimal analgesic technique after VATS anatomic lung resection taking into account pain scores and QoR.

Study design: The proposed multi-centre randomised trial is a three-arm trial comparing PVB, single shot ICNB and TEA in a 1:1:1 ratio for pain (non-inferiority) and for QoR (superiority) in patients who have undergone a thoracoscopic anatomical lung resection.

Main study parameters/endpoints: The NRS (0-10; 0= no pain, 10=worst imaginable pain) will be used to measure pain scores. The primary outcome measure for ‘non-inferiority’ is the proportion of NRS ≥4, defined as the number of NRS ≥4 episodes divided by the total amount of NRS pain scores obtained. The primary outcome for ‘superiority’ is QoR measured with the QoR-15 questionnaire on POD 1 and POD 2.

Study objective

Postoperative pain management by using either regional continuous PVB or single shot ICNB is non-inferior to TEA regarding pain in patients undergoing thoracoscopic anatomical lung resection. Regarding QoR after surgery the unilateral regional techniques are expected to be superior to TEA as scored by the global QoR-15 questionnaire. Signifying faster postoperative mobilisation, reduced morbidity and shorter hospitalization, these techniques may therefore reduce health care costs and improve patient satisfaction.

Study design

T-1: Multidisciplinary oncology meeting: indication for VATS anatomical lung resection
T0: Pre-operative appointment with the lung surgeon at the outpatient clinic
T1: Day of the operation
T2: Postoperative day 1
T3: Postoperative day 2
T4: Postoperative day 3
T5: Hospital discharge

T6: Follow-up at the postoperative appointment with the surgeon at the outpatient clinic

Intervention

Paravertebral block and single shot intercostal nerve block

Contacts

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Eligibility criteria

Inclusion criteria

- Patients referred for anatomical lung resection (pneumonectomy, (bi)lobectomy or segmentectomy) with the intention of performing it by VATS or RATS are eligible for the trial.
- Adult patients older than 18 years who are able to give informed consent and fill out questionnaires in Dutch.

Exclusion criteria

- Contra-indications TEA or PVB (infection at skin site, increased intracranial pressure, non-correctable coagulopathy, bridging indication for therapeutic anticoagulation (CHADS-VASc ≥ 8), sepsis and mechanical spine obstruction)
- Allergy to local anaesthetics
- Chronic use of opioids
- In case the lung surgeon estimates the operation to be performed through a thoracotomy technique instead of a VATS the patient will be excluded.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2021
Enrollment:	571
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
According to our datamanagement plan, the new data that we will generate with the questionnaires about pain, quality of recovery, patient satisfaction and mobility after the operation will be presented as quantitative data. Local researchers and IKNL data managers process the data via the eCRF in the research manager. Associated datasets are encoded as SPSS files.
The agreements about the accessibility, reusability, exchangeability and verifiability of the (new) dataset and about ownership or co-producer of data will be established in writing with each participating center and principal investigator in a research contract.
Written informed consent for participants giving consent to participate in this study (randomization, treatment, data analysis, completion of questionnaires, completion of follow-up) and to reuse data and approach patients for follow-up studies.
We will collaborate with the data archive DANS in order to create data that are findable, accessible, interoperable and reusable (FAIR).

Ethics review

Positive opinion

Date:	01-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52222
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9243
CCMO	NL75375.041.20
OMON	NL-OMON52222

Study results

Summary results
N/A