Optimal postoperative Pain management After Lung surgery

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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...

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

Samenvatting

ID

NL-OMON21054

Bron
NTR

Verkorte titel
OPtriAL

Aandoening

Lung tumor

Ondersteuning

Primaire sponsor: ZonMw, Maxima MC
Overige ondersteuning: ZonMw grant, Maxima MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Paravertebral block and single shot intercostal nerve block

Contactpersonen

Publiek

Maxima Medisch Centrum
Louisa Spaans

0408887243

Wetenschappelijk

Maxima Medisch Centrum
Louisa Spaans

0408887243

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	05-04-2021
Aantal proefpersonen:	571
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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).

Ethische beoordeling

Positief advies

Datum:	01-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52222
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A