Erector Spinae Plane (ESP) Block versus Thoracic Epidural Analgesia (TEA) in Video-Assisted Thoracic Surgery (VATS): A Prospective Randomized Open Label Non-Inferiority Trial

Gepubliceerd: 01-03-2018 Laatst bijgewerkt: 15-05-2024

Effective postoperative pain control is an essential and humanitarian need of every surgical procedure. Inadequate pain control may result in increased mortality, delayed recovery and increased hospital costs (1). The optimal perioperative analgesic...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving nog niet gestart
Type aandoening	Luchtwegen therapeutische verrichtingen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22453

Bron
NTR

Verkorte titel
ESP001

Aandoening

- Luchtwegen therapeutische verrichtingen

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Catharina ziekenhuis Eindhoven
Overige ondersteuning: We applied for internal funding (Catharina Onderzoeksfonds).

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of this study is the QoR15 (See section 6.1.) on POD1 and 2 including subscale analysis Comfort; Emotions, Independence, Support and Pain).

Toelichting onderzoek

Achtergrond van het onderzoek

This is an investigator-initiated prospective randomized open label non-inferiority trial comparing the thoracic epidural (TEA) with the Erector Spinae Plane block (ESP) as regional anesthesia technique for VATS-surgery. The ESP-block is recently introduced in clinical practice as an easy, safe and reliable alternative to the thoracic epidural. This new technique injects local anesthetic within a plane beneath the erector spinae muscle to achieve analgesia (6).

A total of 90 patients are being randomly allocated to ESP (study group) or TEA (control group). Patients will be followed until 48 hours after surgery or until discharge from the hospital. Primary outcome is the Quality of Recovery 15 (QoR15) score. We hypothesize that the ESP is equally as effective as a TEA, without the disadvantages (bedrest, urinary catheter, rare but serious neurologic adverse events).

Doel van het onderzoek

Effective postoperative pain control is an essential and humanitarian need of every surgical procedure. Inadequate pain control may result in increased mortality, delayed recovery and increased hospital costs (1). The optimal perioperative analgesic strategy is preemptive and involves the combined administration of local anesthetic techniques [local anesthetic infiltration, peripheral nerve blocks, and neuraxial blocks (epidural and paravertebral)], systemic analgesic agents (opioids, acetaminophen, non-steroidal anti-inflammatory drugs, and cyclooxygenase-2-specific inhibitors) and analgesic adjuncts such as steroids, ketamine, α-2 agonists, and anticonvulsants (2). This so-called multimodal approach improves the analgesic effect because of the synergizing effect between the different analgesia techniques and/or drugs.

Up until now, the epidural analgesia is the gold standard local anesthetic technique for VATS surgery (3). However, the invasiveness of this technique, the rare but serious neurologic

complications and the failure rates up to 30% (4) have resulted in a search for alternatives. Alternatives include lower thoracic catheter placement, intercostal nerve blocks, paravertebral blocks, intrapleural catheters, local anesthetic infiltration, and systemic analgesia with one or more agents (4). However, none of these techniques were able to replace the thoracic epidural as gold standard due to (5) ‘too technically challenging’ or ‘insufficient analgesia’ (6). Recently the ESP-block has been introduced in clinical practice as an easy, safe and reliable alternative to the thoracic epidural. This new technique injects local anesthetic within a plane beneath the erector spinae muscle to achieve analgesia (6). The most significant advantage of the ESP-block is its simplicity and safety. The sonoanatomy is easily recognizable and there are no structures at risk of needle injury in the immediate vicinity (6). Case reports describe the successful application of the ESP-block for analgesia after VATS surgery (7,8), but evidence from large trials targeting a specific surgical population is lacking. To test the hypothesis that the ESP block with Continuous ESP Analgesia (ESP) is non-inferior in terms of the quality of recovery as measured by the Quality of Recovery 15 (QoR15) score compared to the thoracic epidural with continuous epidural analgesia (TEA) for patients undergoing elective unilateral VATS.

Onderzoeksopzet

Patients will be followed until 48 hours after surgery or until discharge from the hospital. Thirty days after the surgery, patients will be contacted for a telephone survey.

Onderzoeksproduct en/of interventie

Patients will be randomized (1:1) to receive either pain treatment with ESP (the study group) or TEA (the control group). Patients in the intervention group receive continuous ESP analgesia (ESP) with bupivacaine 0.125% and a PCIA pump with morphine. Settings of the continuous ESP analgesia are 10- 15ml/h, settings of the PCIA pump are according to local protocol. When ESP does not provide adequate pain relief, minor adjustments or a manual top-up are allowed. Patients in the control group receive thoracic epidural analgesia (TEA) through a continuous epidural analgesia (CEA) pump with bupivacaine 0.125% + sufentanil 1mcg/ml at 8 - 12ml/h. When CEA does not provide adequate pain relief, minor adjustments or a manual top-up are allowed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria: (1) Age between 18 and 75 years old, (2) BMI between 20 and 30kg/m 2 , (3) scheduled for elective VATS, and (4) written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are as follows: (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-40 questionnaire.

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	26-02-2020
Soort:	Eerste indiening
Toetsingscommissie:	Medical Research Ethics Committees United (MEC-U)

Postbus 2500
3430 EM Nieuwegein
088 320 8784
info@mec-u.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48927
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6433
NTR-old	NTR7224
CCMO	NL65158.100.18
OMON	NL-OMON48927

Resultaten

Samenvatting resultaten

(1) Gupta A, Kaur K, Sharma S, Goyal S, Arora S, Murthy RS. Clinical aspects of acute post-operative pain management & its assessment. J Adv Pharm Technol Res. 2010;1(2):97–108.

(2)Rosero EB, Joshi GP. Preemptive, preventive, multimodal analgesia: what do they really mean? Plast Reconstr Surg. 2014 Oct;134(4 Suppl 2):85S–93S.

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(6)Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The Erector Spinae Plane Block: A Novel Analgesic Technique in Thoracic Neuropathic Pain. Reg Anesth Pain Med. 2016;41(5):621–7.

(7)Scimia P, Basso Ricci E, Droghetti A, Fusco P. The Ultrasound-Guided Continuous Erector Spinae Plane Block for Postoperative Analgesia in Video-Assisted Thoracoscopic Lobectomy. Reg Anesth Pain Med. 2017 Aug;42(4):537.

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