Paravertebral catheter versus epidural analgesia in minimally invasive esophageal resection: a randomized controlled multicenter trial

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Paravertebral analgesia is associated with superior quality of recovery by achieving comparable pain control whilst having less side-effects.

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

Samenvatting

ID

NL-OMON22504

Bron
Nationaal Trial Register

Verkorte titel
PEPMEN

Aandoening

Esophageal cancer

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: ZonMw Doelmatigheid 2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of recovery as measured by the Quality of Recovery 40 (QoR-40) questionnaire on the morning of postoperative day 3.

Toelichting onderzoek

Achtergrond van het onderzoek

Thoracic epidural analgesia is the current standard perioperative pain management modality in esophageal surgery. However, paravertebral analgesia may be an alternative strategy that is associated with equal pain control, but less side effects that contribute to an improved quality of recovery. Therefore, the aim of this multicenter, randomized controlled supriority trial is to compare paravertebral catheter versus thoracic epidural analgesia regarding the quality of recovery, effectiveness of pain control, physical and emotional functioning, side effects, and cost-effectiveness in patients undergoing minimally invasive esophagectomy. Patients who are older than 18 years old, able to provide written informed consent, and scheduled to undergo minimally invasive esophagectomy with an intrathoracic anastomosis and two-field lymphadenectomy (Ivor Lewis procedure) will be included. Randomization will determine whether patients receive paravertebral catheter analgesia combined with patient-controlled intravenous opioids (intervention) or the gold standard of thoracic epidural analgesia (control). A total of 172 patients are required (86 patients in each treatment arm), meaning that 192 patients need to be randomized when assuming 10% loss to follow-up. The primary outcome is the score on the Quality of Recovery-40 (QoR-40) questionnaire on the morning of postoperative day 3. Secondary outcomes include the QoR-40 questionnaire score Area Under the Curve on day 1-3, the integrated pain and systemic opioid score and patient satisfaction and pain experience according to the International Pain Outcomes (IPO) questionnaire, and cost-effectiveness. Furthermore, the following data will be collected: additional rescue medication on day 0-3, opioid consumption on day 0-3, technical failure of the pain treatment, duration of anesthesia time, duration of surgery, total postoperative fluid administration day 0-3, postoperative vasopressor and inotrope use, length of urinary catheter use, length of hospital stay, postoperative complications, chronic pain at six months after surgery, and other adverse effects.

Doel van het onderzoek

Paravertebral analgesia is associated with superior quality of recovery by achieving comparable pain control whilst having less side-effects.

Onderzoeksopzet

Data will be collected preoperatively (baseline), from postoperative day 0 until hospital discharge, at 3 months postoperative follow-up, and at 6 months postoperative follow-up.

Onderzoeksproduct en/of interventie

Paravertebral catheter analgesia combined with patient-controlled intravenous opioids.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who are older than 18 years old, able to provide written informed consent, and scheduled to undergo minimally invasive esophagectomy with an intrathoracic anastomosis and two-field lymphadenectomy (Ivor Lewis procedure) will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ASA >III / severe comorbidity
- Coagulation disorders that prohibit epidural analgesia according to the Nederlandse Vereniging voor Anesthesiologie (NVA) guideline â€œNeuraxisblokkade en antistollingâ€
- Other contraindications for epidural analgesia

- Allergy to local anesthetics
- Chronic opioid use prior to esophagectomy (>3 months)
- Renal failure, i.e. eGFR < 50
- Unable to complete questionnaires in the language of the country in which the trial is conducted
- Cervical lymph node dissection (i.e. 3-field lymphadenectomy)
- Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-12-2019
Aantal proefpersonen:	192
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8037
Ander register	METC UMC Utrecht : 19/588

Resultaten