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

No registrations found.

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

Summary

ID

NL-OMON22504

Source
Nationaal Trial Register

Brief title
PEPMEN

Health condition

Esophageal cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMw Doelmatigheid 2020

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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, cost-effectivenes, 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.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

Paravertebral catheter analgesia combined with patient-controlled intravenous opioids.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

- 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

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):	03-12-2019
Enrollment:	192
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results