Kleine versus GroteTeug Volumes gedurende Een- long Beademing voor Minimaal Invasieve Slokdarmverwijdering - Een Gerandomiseerd Gecontroleerd Onderzoek

No registrations found.

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

Summary

ID

NL-OMON19986

Source
NTR

Brief title
LOCO-trial

Health condition

Minimally invasive esophagectomy
esophageal cancer
lung protective ventilation
small tidal volume ventilation

minimaal invasieve oesophagus resectie
oesofaguscarcinoom
longproectief beademen
kleine teug volumina beademing

Sponsors and support

Source(s) of monetary or material Support: Maestro grant +

fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The main endpoints of this study are markers of pulmonary inflammation and coagulation, including cytokines and chemokines, neutrophil influx, markers of apoptosis, and markers of coagulation and fibrinolysis in lavage fluids obtained at the beginning and at the end of surgery.

Secondary outcome

• Duration of postoperative mechanical ventilation
• Length of stay in intensive care unit and hospital
• Incidence of postoperative pulmonary complications
• Intraoperative hypoxemia
• Anastomotic leakage
• Mortality

Study description

Study objective

We hypothesize a lung–protective mechanical ventilation using lower tidal volumes during general anesthesia for minimally invasive transthoracic esophagectomy to protect against postoperative pulmonary complications in patients undergoing minimally invasive esophagectomy after radiation therapy.

Study design

Before, at the end of, and five days after surgery blood samples will be collected for measurement of:
• Inflammatory mediators (cytokines, chemokines, other inflammatory proteins)
• Markers of lung injury (surfactant proteins A and D)
• Specific markers of distal organ injury (e.g., cystatin C, NGAL)
• Assays for coagulation and fibrinolysis will be measured in the plasma supernatants and bronchoalveolar fluids.

Intervention

to use small tidal volumes during one lung ventilation

Contacts

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Eligibility criteria

Inclusion criteria

Patients planned for elective minimally invasive esophagectomy for esophageal cancer after chemoradiation therapy

Exclusion criteria

- Age < 18 years
- Body mass index > 40 kg/m2
- Chronic obstructive pulmonary disease with a FEV1 of less than 65%
- Preoperative systemic corticosteroid therapy

• Severe cardiac disease (New York Heart Association class III or IV, or acute coronary syndrome, or persistent ventricular tachyarrhythmia’s)
• Altered liver function (Child-Pugh class B or more)
• Neuromuscular disease (any)
• Suspected acute pulmonary infection: In case patient receives antibiotics and meets at least one of the following criteria: new or changed sputum, new or changed lung opacities on chest X–ray when clinically indicated, tympanic temperature > 38.30C, WBC count > 12,000/mm3
• Consented for another interventional study or refusal to participate in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-01-2014
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	NL4246
NTR-old	NTR4391
Other	METC : 12-T-97

Study results

Summary results
N/A