LOw versus COnventional Tidal Volumes during One-lung Ventilation for Minimally Invasive Esophagectomy - A Randomized Controlled Trial

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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…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON37002

Source
ToetsingOnline

Brief title
LOCO-trial

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Lower respiratory tract disorders (excl obstruction and infection)
- Gastrointestinal therapeutic procedures

Synonym
Acute Lung Injury, lung damage

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium/maestro research grant;AMC;Intensive care heerlen

Intervention

Keyword: Acute lung injury, Esophagectomy, One-Lung ventilation, tidal volumes

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

Secondary endpoints include duration of postoperative mechanical ventilation, length of stay in intensive care unit and hospital, incidence of postoperative pulmonary complications and mortality.

Study description

Background summary

Minimally invasive transthoracic esophagectomy is a major surgical procedure with a high risk of postoperative pulmonary complications. It is uncertain whether mechanical ventilation plays a causative role in development of postoperative pulmonary complications.

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

Randomized controlled trial

Study burden and risks

The burden for included patients will be minimal since patients will be anesthetized when the bronchoscopy and broncheo alveolair lavage (BAL) takes place. Also the blood samples will be taken during anesthesia (from an arterial line).
The BAL is a very safe procedure with hardly no risks. There is a slight risk of mucosal bleeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patients who will undergo an esophagectomy

Exclusion criteria

Patients < 18 years
Patients with serious obstructive lung-disease
Patients with NYHA III or IV
Patients with chronic corticosteroid use

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2012
Application type:	First submission

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-10-2017
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd

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
CCMO	NL41619.096.12