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

Published: 10-10-2012 Last updated: 26-04-2024

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

2 - LOw versus COnventional Tidal Volumes during One-lung Ventilation for Minimally ... 25-05-2025

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

#### Public

Atrium Medisch Centrum

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years)

3 - LOw versus COnventional Tidal Volumes during One-lung Ventilation for Minimally ... 25-05-2025

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

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

#### Recruitment

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

# **Ethics review**

Approved WMODate:10-10-2012Application type:First submission

4 - LOw versus COnventional Tidal Volumes during One-lung Ventilation for Minimally ... 25-05-2025

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** CCMO **ID** NL41619.096.12