The effect of Continuous Positive Airway Pressure (CPAP) on the collapsed lung during single-lung-ventilation in patients undergoing robot-assisted thoracoscopic esophageal resection: pulmonary complications, local and systemic cytokine production

Submission date	Recruitment status	Prospectively registered
28/04/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/04/2006	Completed	Results
Last Edited	Condition category	Individual participant data
28/04/2006	Cancer	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

COCTAIL

Study objectives

Continuous positive airway pressure on the deflated lung prevents total alveolar collapse, resulting in less local and systemic cytokine response, causing less pulmonary complications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Esophageal cancer

Interventions

Continuous Positive Airway Pressure (CPAP) to the collapsed lung during single-lung-ventilation versus no CPAP.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Local and systemic cytokine production.

Secondary outcome measures

- 1. Pulmonary complications
- 2. Ventilation time
- 3. Intensive care unit (ICU) stay
- 4. Hospital stay

Overall study start date

05/04/2006

Completion date

05/04/2008

Eligibility

Key inclusion criteria

- 1. Patients with resectable carcinoma of the esophagus or junction that will undergo robotassisted thoracoscopic esophago-lymphadenectomy with gastric conduit formation
- 2. American Society of Anesthesiologists (ASA) classification <4
- 3. Written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

- 1. Moderate/severe lung function impairment ascertained by pulmonary function tests, requiring high dose steroid therapy
- 2. No epidural catheter

Date of first enrolment

05/04/2006

Date of final enrolment

05/04/2008

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Center Utrecht (UMCU)
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation

University Medical Center Utrecht (UMCU), Department of Surgery (The Netherlands)

Sponsor details

Heidelberglaan 100 Utrecht Netherlands 3584 CX

Sponsor type

University/education

ROR

https://ror.org/0575yy874

Funder(s)

Funder type

Research organisation

Funder Name

Comprehensive Cancer Centre (Integraal Kankercentrum)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration