

# 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

<b>Submission date</b> 28/04/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/04/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/04/2006	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr R. Hillegersberg, van

**Contact details**  
University Medical Center Utrecht (UMCU)  
Department of Surgery, G04.228  
Heidelberglaan 100  
Utrecht  
Netherlands  
3584 CX  
+31 (0)30 2506968  
r.vanhillegersberg@umcutrecht.nl

## 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 robot-assisted 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