

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of electrical impedance tomography to optimise mechanical ventilation in laparoscopic bariatric surgery

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Using a new technique to measure lung volume during surgery in obese patients to optimize mechanical ventilation. This study helps to increase safety in these patients during anaesthesia. Electrical impedance tomography is a new technique which allows the estimation of lung volumes during mechanical ventilation. This technique is non-invasive and measures differences in resistance in the skin during mechanical ventilation. There will be no additional strain on the patient. Anaesthesia will be much safer in these patients.

Brief Summary in Scientific Language

**Electrical impedance measurement of lung volume in obese patients
Adjustment of airway pressure according to esophageal pressure measurement via a nasogastral probe**

Organizational Data

- DRKS-ID: **DRKS00004223**
- Date of Registration in DRKS: **2012/06/28**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **PV3867 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs



Health condition or Problem studied

- ICD10: **E66.00** - [generalization E66.0: **Obesity due to excess calories**]
- ICD10: **E66.20** - [generalization E66.2: **Extreme obesity with alveolar hypoventilation**]

Interventions/Observational Groups

- Arm 1: **Electrical impedance tomography measurement of lung volumes in patients undergoing bariatric surgery. Using a non-invasive measurement technique we will determine lung volumes in these patients during mechanical ventilation and adjust airway pressure according to esophageal pressure**
- Arm 2: **Institutional standard respirator setting; PEEP 10 mbar; monitoring using electrical impedance tomography (EIT) and esophageal pressure measurement**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Lung volume measurement using electrical impedance tomography intra/during/post operative in bariatric surgery

Secondary Outcome

Measurement of oxygen saturation pre/intra/post operative using pulse oxymetry

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Hamburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/28**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Bariatric surgery

Exclusion criteria

Children, smoker, preexisting lung disease/esophageal alterations

Addresses

- **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Germany**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/03/25**

Trial Publications, Results and other documents

- Paper [---]*

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.