Trial Description

Title

Respiratory mechanics and ventilation using controlled expiration (FLEX) in lung-healthy adults during elective surgery with general anesthesia.

Trial Acronym

FlexOP-EIT

URL of the trial

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Brief Summary in Lay Language

Surgeries under general anaesthetic require artificial ventilation. We will analyse various measured data of the respiratory tract throughout ventilation. Distribution of air within the lungs will be assessed by electrical impedance tomography (EIT). Collapse of air sacs in small lung-areas (atelectasis) often occurs during artificial ventilation under general anaesthetic. Several methods can be used to prevent this. Our trial will compare two of those methods, to consequently optimize artificial ventilation.

Brief Summary in Scientific Language

Scientific analysis of respiratory mechanics during artificial ventilation in lung-healthy adults has been rather understudied so far. We believe, supported by recent trials, that an elevated positive endexspiratory pressure (PEEP) could potentially prevent ventilator associated lung injury [1,2]. Controlled expiration (FLEX) might be an alternative way to achieve similar effects, without requiring higher PEEP levels [3,4]. This trial assess, how changes throughout the expiration will affect respiratory mechanics (i.e. ventilation and compliance). Therefore, effects of elevated PEEP will be compared with those of controlled expiration (FLEX). Analysis will be conducted using gliding-SLICE-analysis [5,6]. Furthermore, the ventilation and gas distribution within the lungs will be evaluated by electrical impedance tomography (EIT).
Literatur:
[1] Futier et al. A Trial of Intraoperative Low-Tidal-Volume Ventilation in Abdominal Surgery N Engl J Med 2013;369:428-37.
[2] Wirth et al. Intraoperative positive end-expiratory pressure evaluation using the intratidal compliance-volume profile. Br J Anaesth. 2015 Mar;114(3):483-90.
[3] Schumann et al. Determination of respiratory system mechanics during inspiration and expiration by FLow-controlled EXpiration (FLEX) Minerva Anestesiol 2014 Jan;80(1):19-28.
[4] Goebel et al. Flow-controlled expiration (FLEX): A novel ventilation mode to attenuate experimental porcine lung injury British Journal Anaesth 2014 Sep;113(3):474-83.
[5] Schumann et al. Estimating intratidal nonlinearity of respiratory system mechanics: a model study using the enhanced gliding-SLICE Method Physiol Meas 2009 Dec; 30:1341-1356.
[6] Schumann et al. Analysis of dynamic intratidal compliance in a lung collapse

model. Anesthesiology 2011 May;114(5):1111-1117.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00008555**
- Date of Registration in DRKS: **2015/06/05**
- 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.: **163/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **perioperative artificial ventilation**

Interventions/Observational Groups

- Arm 1: **Application of positive endexpiratory pressure (PEEP) of 7mbar only for 5min calibration + 20min measurements,
then application of positive endexpiratory pressure (PEEP) of 5mbar with controlled expiration (FLEX) for 5min calibration + 20min measurements**
- Arm 2: **Application of positive endexpiratory pressure (PEEP) of 5mbar with controlled expiration (FLEX) for 5min calibration + 20min measurements,
then application of positive endexpiratory pressure (PEEP) of 7mbar only for 5min calibration + 20min measurements**

Characteristics

- Study Type: **Interventional**

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- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Perioperative non-linear intratidal compliance, continously measured [ml/mbar] from the end of induction until the end of the surgery

Secondary Outcome

Continuously measured perioperative regional ventilation (using EIT (electrical impedance tomography) - pixel) as well as Oxygenation (SaO2, PaO2), drawn from standard-monitoring, from the end of induction until the end of the surgery

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesthesiologie und Intensivmedizin, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/09**
- Target Sample Size: **30**
- 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

adults of at least 18 years of age, informed written consent, elective surgery, artificial ventilation

Exclusion criteria

known pulmonary disease, cardiac pacemaker, automated implantable cardioverter-defibrillator or other active implants, heart defects, laparoscopic surgery

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/01/01**

Trial Publications, Results and other documents

- Paper **Publikation der Studienergebnisse / Publication of study results**

** 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.*