



Trial Description

Title

Effects of automatic tube compensation on the emergence of auto-PEEP during one-lung ventilation

Trial Acronym

DLT-ATC-Study

URL of the trial

[---]*

Brief Summary in Lay Language

Measurement of the airway pressure is done routinely at the ventilators side and thus away from the lungs of the patient. In double-lumen endotracheal tube (DLT) the flow-resistance and the pressure difference between the pressure in the lungs and the airway pressure is expected to be increased during one-lung ventilation, because of the small inner diameter of the single lumen. The ventilation mode “Automatic Tube Compensation” (ATC) can potentially compensate the difference between the pressure in the lungs and the pressure at the airway opening based on measured airway pressure and flow rate. So far ATC has not been validated during intraoperative one-lung ventilation, although compensation to the intratracheal pressure is of great clinical importance. The study’s aim is to validate ATC during one-lung ventilation with a DLT. Adult Patients who undergo chest-surgery will be included in this study. Using ATC requires the temporary ventilation with an intensive care ventilator (EVITA V500, Dräger Medical, Germany). For the study one-lung ventilation will be performed without and with ATC in a consecutive order. At each ventilation period the ratio of inspiration and expiration is varied. Pressure and flow rate are recorded for a few minutes within the ventilator. This happens during surgery and does not extend the surgical intervention. Based on measured pressure and flow rate the level of dynamic hyperinflation (auto - PEEP) without and with ATC will be determined. It is the hypothesis of the study, that ventilation with ATC will reduce the level of dynamic hyperinflation (auto - PEEP) compared to the ventilation without ATC.

Brief Summary in Scientific Language

The study’s aim is to ventilate 41 adult patients with elective, thoracic surgery without and with the ventilation mode “Automatic Tube Compensation” (ATC) during one-lung ventilation. During controlled mechanical ventilation ATC supports the passive driven expiration, thus reducing the risk of dynamic hyperinflation (auto - PEEP). For the purpose of the study, the patients’ ventilated lung will be ventilated without and with ATC in a consecutive order, using an intensive care ventilator (EVITA V500, Dräger Medical, Germany). During both ventilation intervals the ratio of inspiration to expiration will be varied from 1:2 to 2:1 and the respective level of auto-PEEP will be calculated at each I:E ratio and ventilation mode. Airway pressure and flow rate will be recorded in the ventilator.



We hypothesize that ventilation with ATC will reduce the level of dynamic hyperinflation (auto - PEEP) compared to the ventilation without ATC.

Organizational Data

- DRKS-ID: **DRKS00008849**
- Date of Registration in DRKS: **2015/06/25**
- 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.: **156/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **dynamic hyperinflation**

Interventions/Observational Groups

- Arm 1: **Order of interventions in the individuum (Cross-over design):**
 - (1) One lunge ventilation with inspiration to expiration ratio of 1:2 without Automatic Tube Compensation (ATC). Calculation of dynamic Hyperinflation (auto-PEEP).**
 - (2) One lunge ventilation with inspiration to expiration ratio of 1:2 with Automatic Tube Compensation (ATC). Calculation of dynamic Hyperinflation (auto-PEEP).**
 - (3) One lunge ventilation with inspiration to expiration ratio of 2:1 without Automatic Tube Compensation (ATC). Calculation of dynamic Hyperinflation (auto-PEEP).**
 - (4) One lunge ventilation with inspiration to expiration ratio of 2:1 with Automatic Tube Compensation (ATC). Calculation of dynamic Hyperinflation (auto-PEEP).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*



Study Type: **Interventional**

Study Type Non-Interventional: [---]*

- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Dynamic Hyperinflation (auto-PEEP) in mbar

Secondary Outcome

Airway pressure, calculated bronchial pressure, flow, tidal volume, endexpiratory CO₂, heartrate, mean arterial blood pressure, arterial oxygenation

Countries of recruitment

- DE **Germany**

Locations of Recruitment

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

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/13**
- Target Sample Size: **41**
- 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

Thoracic surgical procedure requiring one lung ventilation

Exclusion criteria

Pregnancy, terminal illness, intraoperative desoxygenation, emergency operation, language barrier

Addresses

■ **Primary Sponsor**

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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): **2015/12/01**

Trial Publications, Results and other documents

* 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.