Trial Description

Title

Activation of respiratory muscles during weaning from mechanical ventilation

Trial Acronym

wEanMG

URL of the trial

[---]*

Brief Summary in Lay Language

Mechanical ventilation is often required in severe disease. The process of withdrawal of mechanical ventilation and establishment of breathing without ventilatory support is called „weaning“.

In long-term mechanical ventilation a tracheostomy is commonly performed. In long-term ventilation, respiratory muscles become less efficient and loose strength. Training of these weak respiratory muscles is the main aspect during weaning. However, overstressing these muscles in weaning is contraproductive and must be avoided.

Several previous studies have shown that different ventilator settings, body posture or spontaneous breathing may induce an elevated load on the respiratory muscles.

It is the aim of this study to assess the activation of the respiratory muscles during spontaneous breathing in different body postures. Surface electromyography is a noninvasive technique for assessing the electrical potential elicited by muscular action and allows objective measures of muscular function.

Brief Summary in Scientific Language

The main goal of the study is to express the effects of different body position (flat in bed, 30° elevated torso, sitting in bed) onto the respiratory muscles during spontaneous breathing trials. Furthermore, muscle activation during invasive ventilation and decanulation are to be assessed.
Parasternal muscles, the diaphragm and exspiratory muscles (M. rectus abdominis) will be measured using surface electromyography (EMG). Surface EMG is a noninvasive, painless and reproducible method of assessing muscular activation. EMG parameters will be correlated with physiological paramaters, such as breathing frequency, tidal volume, minute ventilation, oxygen saturation, heart rate and blood pressure.
The different body positions will be applied in randomized order.

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

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003447**
- Date of Registration in DRKS: **2012/01/18**
- 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.: **447/11 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1126-5775**

Health condition or Problem studied

- ICD10: **J96.99 - [generalization J96.9: Respiratory failure, unspecified]**

Interventions/Observational Groups

- Arm 1: **Body position: flat in bed, spontaneous breathing trial**
- Arm 2: **Body position: 30° elevated torso, spontaneous breathing trial**
- Arm 3: **Body position: sitting in bed, spontaneous breathing trial**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
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Allocation: **Randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: **[---]***

- Control: **Active control**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary endpoint is the muscular activation in contrast to maximal voluntary activation in the distinct muscular groups in three different body positions (%max) (flat, 30° elevated torso, sitting in bed) as assessed by surface EMG of the respiratory muscles (parasternal, diaphragm, M. rectus abdominis)

Secondary Outcome

Secondary endpoints are differences in muscular activation with respect to maximal voluntary activation as assessed by surface EMG of the respiratory muscles between sitting with blocked tracheal canula and decanulation. Furthermore differences in muscular activation during mechanical ventilation with regard to body position and changes in minute ventilation during changing body positions.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Pneumologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2012/01/23**
- Target Sample Size: **20**

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- 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

Patients during prolonged weaning will be recruited at the time point when at least 30min of spontaneous breathing can be performed without cardiorespiratory deteriorations. Patients should be tracheotomized with canula size ID 7,5 / 8.

Exclusion criteria

Exclusion criteria are neuromuscular diseases, acute infections, minimal cooperation, implanted electrical devices or orthopedic limitations for certain body positions as requested by the study design.

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

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.*