Trial Description

Title

Diaphragmatic strength during respiratory muscle training in weaning patients

Trial Acronym

TracheoTwitch

URL of the trial

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Brief Summary in Lay Language

This study examines the acute effects of respiratory muscle training on the diaphragm in difficult to wean ventilator-depended patients. Respiratory muscle training is an aid in the weaning process.
This study includes tracheostomized patients that can manage to maintain spontaneous ventilation for at least one hour. This study aims to show that respiratory muscle training is a safe procedure in these patients without acute effects on diaphragmatic force generation.

Brief Summary in Scientific Language

Previous studies have shown that respiratory muscle trainings (RMT) is a feasible tool in tracheostomized difficult to wean patients resulting in improved inspiratory muscle strength (PImax) and weaning duration. However, selective effects of RMT on ventilator-induced diaphragmatic dysfunctin (VIDD) have not been shown so far.
It is the aim of this study to examine the acute effects of RMT on diaphragmatic function and –strength. The diagnosis of VIDD is going to be stabilshed two-fold in these patients: applying ultrasound guided motion analysis of the diaphragm and magnetic bilateral anterior phrenic nerve stimulation (BAMPS) with pressure assessment at the tracheal canula (TwPet).
RMT is going to be performed using a commercially available tool (Threshold IMT / PEP, Philips-Respironics) as an inspiratory threshold loading regime.
The acute effects of RMT will be assessed using physiological parameters (breathing frequency, heart rate, blood pressure, blood gas analysis, heart minute volume), estimates of respiratory drive (surface electromyography of the parasternal muscles and the diaphragm) and diaphragmatic strength assessment using BAMPS and TwPet.

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: **DRKS00004813**
- Date of Registration in DRKS: **2013/05/22**
- 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.: **104/13 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1140-2727**
- Sponsor-ID: **[---]***
- Other Secondary-ID: **[---]***

Health condition or Problem studied

- ICD10: **J96.19 - [generalization J96.1: Chronic respiratory failure]**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **Following the explanation of the study and the signing of the informed consent of the participant on the day prior to the measurement, the patient is transferred to mechanical ventilator, suitable for the study conditions and the parameters are adjusted to the patients best comfort. Following adaptation to the ventilator, the electromyography electrodes are placed onto the respiratory muscle groups (parasternal muscles,diaphragm) in a sitting position. After confirmation of correct electrode placement, tests of voluntary respiratory muscle strength (PImax) are performed. Careful placement of the magnetic phrenic nerve stimulation coils anterolateral to the neck and stimulations are carried out to assure supramaximal phrenic nerve stimulation according to the tracheal tube twitch pressure (TwPet (Powerlab, AdInstruments Pty, Castle Hill, Australien)). In the time span between PImax and TwPet measurements the patient will be breathing unassisted at the tracheal tube, if needed with oxygen supply.**
  Prior to respiratory muscle training (RMT, (in total 4 training sessions lasting 1 min each with 2min break in between using Threshold IMT bzw PEP, Fa. Philips-Respironics)) TwPet will be assessed (T0). Four trainings sessions will be performed; TwPet will be performed following every second RMT session (T1,

**T2), as well as 5min (T3) and 15min (T4) post RMT.
At the above mentioned time points physiological parameters will be assessed as follows: respiratory muscle activation (EMG and, physiological parameters (breathing frequency, heart rate, blood pressure, blood gas analysis, heart minute volume)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint is the course of tracheal-canula airway pressure (TwPet (Powerlab, AdInstruments Pty, Castle Hill, Australien)) during bilateral anterior magnetic phrenic nerve stimulation (BAMPS(Magstim 2002, Magstim Inc. ,Wales, United Kingdom)) pre and post respiratory muscle training (IMT) at the time points T0 (before training) and T2 (after 4 RMT sessions).

Secondary Outcome

The course of maximal static inspiratory pressure (PImax), electrical respiratory muscle activation as assessed by electroymography (EMG), blood gas parameters, subjective dyspnea and strength assessment (modified Borg Dyspnea Scale), breathing rate, heart rate, blood pressure during respiratory muscle training at the time points T0 (before training), T1 (after 2 RMT sessions, T2 (after 4 RMT sessions, T3 and T4 (5min and 15min post RMT).

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: **2013/06/03**
- Target Sample Size: **16**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Prolonged Weaning according to the criteria of Boles et al Weaning from mechanical ventilation. Eur Respir J. 2007; 29: 1033-56.
Ability fo spontaneus unassisted breathing for at least one hour
Informed consent
Supplied with a tracheostomy tube
At least 18 years of age

Exclusion criteria

Severe hypoxic respiratory insufficiency(PaO2 < 60mmHg with an FiO2 > 0.40)
Hemodynamic instability within the previous 24h to the study with increased levels of catecholamines (Dobutamin > 5 mg/kg/min, Noradrenalin > 1 mg/kg/min)
Previous known neuromuscular diseases (other than critical illness polyneuropathy (CIP)/-myopathy (CIM), intensive care unit acquired weakness (ICUAW))
Lacking cooperation
Implanted metal devices in the head/neck region
Orthopedic or other limitations for a sitting position
Use of sedative or analgetic medication within 6 hours prior to the measurement
Indication to use a PEEP-ventile for unassisted spontaneous breathing
Body Mass index > 30 kg/m2

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 planned**
- 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.*