Trial Description

Title

espiratory muscle activation by respiratory muscle training in patients with advanced COPD

Trial Acronym

EMG-Train COPD

URL of the trial

[---]*

Brief Summary in Lay Language

This study aims at assessing the activation of respiratory muscles by respiratory muscle training in patients with chronic obstructive pulmonary disease (COPD). So far respiratory muscle training has been proven to have benefitial effects in healthy subjects and patients with pulmonary diseases such as COPD.

In this study respiratory muscle activity wil be assessed by noninvasive electromyography, which can be compared to writing an ECG. Subjects will perform two bouts of respiratory muscle training with two different modes of respiratory muscle training.

Brief Summary in Scientific Language

This study aims at examining two modes of respiratory muscle training (Inspiratory threshold loading (ITL) and targeted resistive breathing (TRB)) with respect to respiratory muscle activation (M. sternocleidomastoideus, 2nd intercostal parasternal muscles, diaphragm) by noninvasive surface electromyography in patients with advanced COPD.

Organizational Data

- DRKS-ID: **DRKS00005637**
- Date of Registration in DRKS: **2014/02/04**
- 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.: **36/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1152-0307**
- Other Secondary-ID: **[---]***

Health condition or Problem studied

- ICD10: **J44.89 - message.icd10.coding.redirected.en**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **After obtaining written informed consent from the patients, spirometry and blood gases will be measured. EMG electrodes will be positioned in a semi-rucumbent position after cleansing the skin wih alcohol and abrasive paste. Signal quality will be checked while performing maximal respiratory maneuvers (Plmax, Sniff-pressure, breathing to toal lung capacity).**
  Then respiratory muscle training (ITL: 2 sets lasting 1min with a break of 3min, TRB: 2 sets lasting 45sec with a break lasting 3min) will be performed in a randomized order. Patients will be sitting in a standardized position in order to minimize postural contamination of the EMG signal. Between the training sessions a 30min rest will be held. Before and after each training session spirometry and blood gases will be measured.
  Study session 1: TRB: targeted resistive breathing: patients will perform controlled breathing through a defined stenosis, applied by a commercially available training device (RespiFit S)
- Arm 2: **Study session 2: ITL. inspiratory threshold loading: patients breathe through a dedicated respiratory muscle training device (PowerBreath that applies a defined load onto respiration.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- 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

Differences in parasternal respiratory muscle activation (expressed as % of

acitvation during maximal voluntary breathing maneuvers) applying electromyography during different modes respiratory muscle training (ITL vs TRB). Data recording and evaluation will be during the last breaths of each respiratory training session.

Secondary Outcome

- resting EMG of the respiratory muscles (M. sternocleidomastoideus, parasternal muscles, diaphragm) for the right / left body side
- maximal innervation as assessed by EMG during maximal voluntary breathing maneuvers (PImax, Sniff, TLC-breathing)
- effect of respiratory muscle training on dynamic hyperinflation, as assesse by spirometric measurement of the inspiratory capacity

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/10**
- Target Sample Size: **15**
- 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 with advanced stable hypercapnic COPD and éstablished noninvasive mechanical ventilation

Exclusion criteria

- severe hypoxia ((PaO2 < 60mmHg despite oxygen supplementation)

- haemodynamic instability within the last 24h
- neuromuscular disease
- acute infectin (procalcitonin >10 ng/ml and/or CRP > 10 mg/dl)
- missing cooperation
- use of sedative or analgetic agents within the last 6h
- body mass index > 30 kg/m2

Addresses

■ **Primary Sponsor**

Uniklinik Freiburg, Department für Innere Medizin, Klinik für Pneumologie
Mr. Dr. med. Stephan Walterspacher
Killianstr. 5
79106 Freiburg
Germany

Telephone: **+49 761 270-37060**
Fax: **+49 761 270-37040**
E-mail: **stephan.walterspacher at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/pneumologie/live/index.html**

■ **Contact for Scientific Queries**

Uniklinik Freiburg, Department für Innere Medizin, Klinik für Pneumologie
Mr. Dr. med. Stephan Walterspacher
Killianstr. 5
79106 Freiburg
Germany

Telephone: **+49 761 270-37060**
Fax: **+49 761 270-37040**
E-mail: **stephan.walterspacher at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/pneumologie/live/index.html**

■ **Contact for Public Queries**

Uniklinik Freiburg, Department für Innere Medizin, Klinik für Pneumologie
Mr. Dr. med. Stephan Walterspacher
Killianstr. 5
79106 Freiburg
Germany

Telephone: **+49 761 270-37060**
Fax: **+49 761 270-37040**
E-mail: **stephan.walterspacher at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/pneumologie/live/index.html**

Sources of Monetary or Material Support

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

Uniklinik Freiburg, Department für Innere Medizin, Klinik für Pneumologie
Mr. Dr. med. Stephan Walterspacher
Killianstr. 5
79106 Freiburg
Germany

Telephone: **+49 761 270-37060**
Fax: **+49 761 270-37040**
E-mail: **stephan.walterspacher at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/pneumologie/live/index.html**

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.*