Trial Description

Title

Respiratory muscle activation in COPD during noninvasive mechanical ventilation

Trial Acronym

HiLo NPPV

URL of the trial

[---]*

Brief Summary in Lay Language

**Noninvasive ventilation (NIV) is established in treating patients with chronic hypercapnic respiratory failure due to chronic obstructive pulmonary disease (COPD).
In recent years different forms of NIV have been established. It remains unknown so far, which ventilation mode is best in unloading the respiratory muscles.
This study aims at assessing respiratory muscle unloading in three different settings of NIV by non-invasive surface electromyography of the respiratory muscles. Each ventilation session will be held for 30min.
This study aims at evaluating which mode of NIV is most favorable for respiratory muscle unloading. Study subjects will be recruited during their routine vivits in our respiratory department for checkup of the established NIV due to COPD.**

Brief Summary in Scientific Language

**This study aims at assessing respiratory muscle activation during three different modes of noninvasive ventilation (NIV) in patients with chronic hypercapnic respiratory failure due to COPD and established NIV.
Respiratory muscle unloading will be assessed by noninvasive surface electromyography (EMG) of M. sternocleidomastoideus, parasternal muscles and the diaphragm during ventilation periods of 30min in each study mode. Prior and post each ventilation session lung function parameters will be assessed.**

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005639**
- Date of Registration in DRKS: **2014/02/06**
- 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.: **37/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1152-0333**
- Other Secondary-ID: **[---]***

Health condition or Problem studied

- ICD10: **J44.89 - [generalization J44.8: Other specified chronic obstructive pulmonary disease]**

Interventions/Observational Groups

- Arm 1: **Following blood gas measurements and siprometry the patient will be put in a sitting position. Surface-EMG electrodes will be placed after desinfection and cleansing of the skin.**
  Signal quality will be checked by performing maximal volunatry breathing maneuvers (PImax, Sniff, TLC-breathing).
  The different modes of NIV will be performed in a randomized order in a half-sitting position. Each ventilation mode will be performed for 30min; there will be 15min of rest between each study session. NIV will be performed with the NIV-masks for the individual therapy.
  Setting 1: low-intensity NIV - pressure settings will be set according to the previous study performed by our group.
- Arm 2: **Setting 2: high-intensity NIV as established for chronic NIV with high backup breathing rate**
- Arm 3: **Setting 3: (established) high-intensity NIV with low backup breathing rate**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

Blinding: **[---]***

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

Control: **Active control**

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

Primary Outcome

Differences in parasternal respiratory muscle activation applying electromyography during different modes of noninvasive mechanical ventilation with respect to maximal volitional respiratory muscle activation.

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)
- sensation of dysnpoea during different modes of noninvasive mechanical ventilation

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik für Pneumologie, Uniklinik Freiburg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/10**
- Target Sample Size: **20**
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(Anticipated or Actual) Date of First Enrollment: **2014/02/10**

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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 with advanced stable hypercapnic COPD and established 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**

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- **Contact for Scientific Queries**

Uniklinik Freiburg, Department für Innere Medizin, Klinik für Pneumologie

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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.*