

Trial Description

Title

Acute impact of inspiratory muscle training on patients with stable hypercapnic COPD

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Numerous studies have revealed that patients with chronic obstructive pulmonary disease benefit from inspiratory muscle training. However the acute impact of inspiratory muscle training on patients with chronic obstructive pulmonary disease and respiratory insufficiency (elevated levels of carbon dioxide partial pressure (PaCO₂) and decreased levels of oxygen partial pressure in the blood) still remains unclear. Therefore this study aims to investigate the acute effects of a training cycle of inspiratory muscle training on carbon dioxide partial pressure, inspiratory muscle strength and oxygen saturation in patients with COPD and chronic respiratory insufficiency.

Brief Summary in Scientific Language

Numerous studies have revealed that patients with COPD benefit from inspiratory muscle training (IMT). However the acute effect of IMT in COPD patients with stable hypercapnic respiratory insufficiency still remains unclear. Especially the question whether IMT leads to an increase in PaCO₂ and a decrease of inspiratory muscle strength directly after an IMT cycle still needs to be answered. The aim of the current study is to investigate if IMT leads to an acute change of PaCO₂, oxygen saturation and inspiratory muscle strength in 20 COPD patients with stable hypercapnic respiratory insufficiency.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

■ DRKS-ID: **DRKS00004221**

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- Date of Registration in DRKS: **2012/07/17**
- 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.: **155/12** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44.9 - Chronic obstructive pulmonary disease, unspecified**
- ICD10: **J96.11 - [generalization J96.1: Chronic respiratory failure]**

Interventions/Observational Groups

- Arm 1: **20 COPD patients with stable hypercapnic respiratory insufficiency perform a cycle of inspiratory muscle training (30 breaths). Before and after a training cycle capillary blood gas analysis and respiratory muscle function tests will be performed. After a 15 min break, another cycle of inspiratory muscle training (30 breaths) will be initiated followed by another blood gas analyses and respiratory muscle function tests. Transcutaneous CO2 is assessed during the whole protocol.**

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: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
-



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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

Development of capillary carbon dioxide partial pressure (PaCO₂) after a session of inspiratory muscle training

Secondary Outcome

Development of twitch mouth pressure after magnetic stimulation of the phrenic nerves before and after a session of inspiratory muscle training

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/27**
- Target Sample Size: **20**
- 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

stable hypercapnic COPD Patients

Exclusion criteria

Patients with neuromuscular diseases, thoracic deformity, respiratory infections, pregnancy, pH below 7,33

Addresses

■ Primary Sponsor

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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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Kennedyallee 40
53175 Bonn
Germany**

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URL: **www.dfg.de**

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

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Status

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

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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.*