



PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Influence of NPPV on development of inspiratory muscle fatigue during submaximal ergometric load

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Influence of NPPV on development of inspiratory muscle fatigue during submaximal ergometric load

Brief Summary in Scientific Language

Determine the influence of NPPV on development of inspiratory muscle fatigue during submaximal ergometric load

Organizational Data

- DRKS-ID: **DRKS00000009**
- Date of Registration in DRKS: **2008/09/05**
- 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.: **153/06 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF000899 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied



- ICD10: **J98.6 - Disorders of diaphragm**

Interventions/Observational Groups

- Arm 1: **NPPV**

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: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Blood lactate and blood gas values from the arterialized ear lobe, heart rate, P_{lmax}1.0, twitch pressures and cycling time to exhaustion. These measurements were conducted five times on each study phase (labeled I to V): before and immediately after each HEET as well as during the recovery period

Secondary Outcome

[---]*

Countries of recruitment

- **DE Germany**

Locations of Recruitment



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/02/01**
- Target Sample Size: **10**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

healthy, male subjects, >18 years of age

Exclusion criteria

any preexisting disease

Addresses

■ Primary Sponsor

**Universitätsklinikum Freiburg
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Sources of Monetary or Material Support

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Paper **The Open Respiratory Medicine Journal, 2008, 2, 16-21
1874-3064/08 2008 Bentham Science Publishers Ltd.
Non-Invasive Ventilation Applied for Recovery from Exercise-Induced
Diaphragmatic Fatigue
Hans-Joachim Kabitz*, David Walker, Stephan Prettin, Stephan Waltersbacher,
Florian Sonntag, Michael Dreher and Wolfram Windisch**

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* *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.*