



Trial Description

Title

Perfusion of peripheral muscles during isolated exercise of respiratory muscles in hypoxia and normoxia

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

It is known that respiratory muscle loading, as it occurs during intensive whole body exercise can lead to a temporary fatigue of the respiratory muscles. This respiratory muscle fatigue can cause a reduction of limb blood flow through a reflex called the respiratory metaboreflex. It is also known, that loading the respiratory muscles in an environment with less oxygen (hypoxia) increases the development of respiratory muscle fatigue. However it is so far not known, whether respiratory muscle loading in hypoxia leads to an increased reduction of the limb blood flow compared to respiratory muscle loading in an environment with normal oxygen availability (normoxia). This is the purpose of the present study. 12 healthy subjects between 18 and 40 years of age will undergo 20 minutes of isolated respiratory muscle loading in hypoxia and normoxia. Before, during and after respiratory muscle loading we will assess the blood flow in the leg muscles by using contrast enhanced ultrasound and conventional duplex sonography.

Brief Summary in Scientific Language

It is known, that respiratory muscle loading as it occurs during intensive whole body exercise can lead to a temporary fatigue of the respiratory muscles. This respiratory muscle fatigue can cause a reduction of limb blood flow through a reflex called the respiratory metaboreflex. It is also known, that respiratory muscle loading in hypoxia increases the development of fatigue compared to normoxia. However it is so far not known, whether respiratory muscle loading in hypoxia leads to an increased metaboreflex and a further reduction of limb blood flow compared to respiratory muscle loading in normoxia. This is the purpose of the present study. 12 healthy subjects between 18 and 40 years of age will undergo 20 minutes of isolated respiratory muscle loading at 60-80% of P_{imax} in hypoxia and normoxia. Before, during and after respiratory muscle loading in hypoxia and normoxia muscle perfusion of the calf muscle will be assessed by using contrast enhanced ultrasound and blood flow in the popliteal artery is measured by conventional duplex sonography. Primary objective of this study is the difference in calf muscle perfusion during isolated respiratory muscle loading in hypoxia compared to normoxia.

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

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004631**
- Date of Registration in DRKS: **2013/01/10**
- 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.: **488/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Sponsor-ID: [---]*
- Other Secondary-ID: [---]*

Health condition or Problem studied

- Free text: **Muscle perfusion of the lower extremity in hypoxia and normoxia during inspiratory muscle loading in healthy volunteers**
- Free text: **Comparison of arterial blood flow and muscle perfusion during respiratory muscle loading**
- Free text: **healthy volunteers**

Interventions/Observational Groups

- Arm 1: **Pre-measurements: To begin, subjects perform a bodyplethysmography and measurement of maximal inspiratory mouth pressure (Pimax) to assess respiratory muscle strength. Then diaphragmatic strength is measured at rest at different lung volumes ranging from residual volume to total lung capacity by mouth pressure measurement after bilateral anterior magnetic stimulation of the phrenic nerve (TwPmo). Subjects perform inspiratory muscle loading single blinded and in randomized order of hypoxia and normoxia on two separate days. Before and after the inspiratory muscle loading, subjects diaphragmatic contractility is assessed at rest in normoxia.**

Study arm I (hypoxia): Subjects begin breathing oxygen reduced air and the

hypoxia study arm is begun. Before, during and after respiratory muscle loading a duplexsonography of the popliteal artery and a contrast enhanced sonography of the calf muscle is performed. For the application of the contrasting agent a peripheral venous catheter is placed in the antecubital fossa or forearm and the wash-in of the contrasting agent is measured in the calf muscle by ultrasound. The inspiratory muscle training device is set at a workload of 60-80% of the individual's maximal inspiratory pressure (P_Imax). Hypoxia is generated using a special device which simulates altitude by adding nitrogen to the air-mixture the subjects inhale. By individually setting the subject's FiO₂ we can sustain their oxygen saturation at 80% during the hypoxia protocol. Additionally we will monitor the subject's end tidal and transcutaneous CO₂ and, to ensure normocapnia, will change their FiCO₂ in case of hyperventilation. Before and after respiratory muscle loading a blood gas analysis is performed. Respiratory muscle loading is carried out for 20 minutes, then the hypoxia is terminated and measurements of diaphragmatic contractility by assessment of TwP_{mo} are performed in normoxia.

- **Arm 2: Study arm II (normoxia): As in arm I a 20 minute loading of the respiratory muscles is performed by each subject. Before and afterwards TwP_{mo} is assessed. Before, during and after respiratory muscle loading at exactly corresponding times to those in hypoxia blood flow of the popliteal artery and perfusion of the calf muscle is measured using duplex sonography and contrast enhanced ultrasound.**

Characteristics

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

Difference in contrast medium travel time after 20 minutes of inspiratory muscle loading in hypoxia in contrast to normoxia.

Secondary Outcome

Difference in blood flow (assessed by duplex sonography) after 20 minutes of inspiratory muscle loading in hypoxia in contrast to normoxia.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Forschungsgruppe Atemphysiologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/09**
- Target Sample Size: **12**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

Age > 18 years, normal lung function

Exclusion criteria

acute coronary syndrome, congenital heart defects, pulmonal hypertension, neuromuscular diseases, deformities of the thorax, respiratory infections, pregnancy and lactation, cardiac pacemaker, AICD, electric / metal implants

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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**Deutsches Register
Klinischer Studien**

German Clinical
Trials Register

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

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Fax: [---]*

E-mail: [---]*

URL: **www.uniklinik-freiburg.de**

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.