



## Trial Description

### Title

**Physiologic changes of cardiocirculatory parameters in normobaric hypoxia**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Twelve healthy volunteers will be exposed to normobaric hypoxia in an air-conditioned chamber. Oxygen partial pressure will be adjusted by replacing oxygen by nitrogen and simulate an height of 4000m and 5500m above sea level in order to investigate different cardiovascular parameters compared to baseline.**

### Brief Summary in Scientific Language

**The physiologic changes during exposition of high altitude are incompletely understood. To investigate the influence of low oxygen to different organ systems healthy subjects will be exposed to low oxygen concentration simulating altitude. Different physiological changes will be investigates.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00005459**
- Date of Registration in DRKS: **2013/11/21**
- 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.: **2749-01/10** , **Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **T70.2 - Other and unspecified effects of high altitude**
- Free text: **Mountain sickness**
- Free text: **Healthy volunteers**

## Interventions/Observational Groups

- Arm 1: **All subjects will undergo a baseline measurement followed by exposition to normobaric hypoxia in two steps (4000m, 5500m). An exercise challenge at the end is optional.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]\***
- Who is blinded: **[---]\***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**3D-Echokardiography (Torsion and Twist of left and right ventricle, PA-pressure, Vitien. Measurements Baseline and 5500m). Laser-doppler (flow profiles, Fourier-Analysis: Baseline and 5500m), Laboratory values (blood count, Cytokines, BNP, Troponin, thrombocyte function; baseline, 4000 and 5500m), Count of circulating regulatory T-cells (Baseline, 5500m), dendritic cells (Baseline, 5500m), Metabolomics (Baseline, 4000m, 5500m), Protein expression of erythrocytes (Baseline, 4000m, 5500m). Retinal vessel analysis (Baseline, 5500m).**

## Secondary Outcome

[---]\*

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Jena**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/11/24**
- Target Sample Size: **12**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

## Additional Inclusion Criteria

**Willingness to participate**

## Exclusion criteria

**Signifikant morbidity in the past**

## Addresses

- **Primary Sponsor**  
**Universitätsklinikum Jena**  
**Bachstraße 18**  
**07740 Jena**  
**Germany**



### **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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## 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.