

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

Trial Description

Title

Vibration Bed Rest Study

Trial Acronym

VBR

URL of the trial

[---]*

Brief Summary in Lay Language

Immobilisation over several weeks or months leads to a decrease of bone and muscle mass and to severe decreases in power and strength of skeletal muscle. Additionally, immobilisation leads to a deconditioning of the cardio-vascular system and to changes in the fluid regulation of the human body. These effects can be caused by immobilisation as in injury or illness and they also occur after a stay in microgravity. The Vibration-Bed-Rest-Study (VBR-Study) was performed to investigate the potential of whole body vibration training to counteract degenerative effects of 14 days of 6° head down tilt bed rest (6°-HDT bed rest) on the human body. The effects of immobilization with and without vibration training on different tissues and organs, including skeletal muscle performance, balance performance and articular cartilage, were determined. In the VBR-Study 8 healthy male subjects were investigated. They stayed stationary for 2 time 23 days in the clinical ward of the German Aerospace Center (DLR) in Cologne. During 14 days in each study phase they received 6°-HDT. In one of the study phases they received vibration training in the other the control intervention. For skeletal muscle we investigated the changes of force production and power, muscle mass, muscle metabolism and hormones of muscle metabolism. Bone metabolism was investigated using biomarker of bone formation and resorption. Additionally, systemic changes of acid-base balance and regulation of the cardio-vascular-system and fluid regulation was investigated.

Brief Summary in Scientific Language

Similar as a stay in microgravity immobilisation leads to a decrease in bone and muscle mass. Also physiological adaptations in the cardio-vascular-system and fluid regulation on the body occur. The main objective of the study is to test the potential of whole body vibration training to counteract the deconditioning and the atrophy of bone and muscle tissue during immobilisation. The physiological effects of microgravity can be simulated using bed rest in 6° head down tilt (HDT), meaning the whole bed is tilted 6° toward the head. In high performance sports and in rehabilitation and prevention programs whole



body vibration training became popular as a complement to regular strength training (Jordan et al., 2005) in an attempt to increase the efficiency of strength training that may affect all tissues of the musculoskeletal system. The athlete exercises on a motor driven vibration platform which leads to an additional mechanical stimulus. Current research is conducted to find the optimal combination of different variables such as training intensity, frequency and amplitude of the vibration, mechanical characteristics of the vibration input and others that would result in a positive response in terms of an anabolic reaction in training processes. Recent studies show that the time effort is smaller using vibration training as compared to regular strength training (Cardinale and Bosco, 2003). It has also been reported, that vibration training increases the sensitivity of receptors such as muscle spindles, which leads to an increase in force production (Hagbarth and Eklund, 1966; Cardinale and Bosco, 2003) and the training method positively influences muscle related hormone status (Bosco et al. 2000). All these effects have been investigated under normal gravity conditions on earth; however, the training method is of high interest for the physical training for astronauts. Preparing the body for the travel into microgravity, the prevention of physical fitness during the flight and the rehabilitation after return to earth are very important elements in the daily routines of astronauts. The results that have been published in the context of vibration training allow the presumption that this training method could help to optimize the training methods astronauts are currently using.

The objective if the VBR-study is to investigate the potential of whole body vibration training to counteract the effect of prolonged bed rest on the human body.

The study will be performed with 8 healthy male subjects who will be stationary in the clinical ward of the DLR for 2 times 23 days. During 14 days in each study phase they will receive 6°-HDT.

The measured variables before and after the bed rest period will be muscle metabolism, muscle mass and performance, biomarkers of bone metabolism, hormones connected to muscle metabolism, changes in acid-base balance, fluid regulation and changes in the cardio-vascular-system.

In summary the following questions will be answered:

Organizational Data

- DRKS-ID: **DRKS00000140**
- Date of Registration in DRKS: **2009/07/13**
- 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.: **2004139 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs



- Universal Trial Number (UTN): **U1111-1111-2961**

Health condition or Problem studied

- Free text: **muscle atrophy, bone resorption, deconditioning of the cardio vascular system, deconditioning of the balance ability, cartilage degeneration**

Interventions/Observational Groups

- Arm 1: **Subject are immobilized for 14 days using 6° head down tilt bed rest. Twice a day they walk to the training room and stand for 5 x 1 minute on the turned off vibration platform. Inbetween the repetitions they sit for 5 x 1 minute on a chair.**
- Arm 2: **During 14 days of 6°-head down tilt bed rest subjects train two times per day for 5x 1 minute with whole body vibration training. For the training a commercial vibration platform is used (Galileo 900) and subjects train with a frequency of 20Hz and an amplitude of 2-3mm. During the training they stand in a stationary position with a knee flexion angle of 30° and an additional weight of 15% body weight on the platform. Inbetween the repetitions subject rest for 5 x 1 Minute on a chair.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Non-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): [---]*

Primary Outcome

Is vibration training able to decelerate or prevent muscle atrophy during 14 days of bed rest? || Changes in Biomarkers of bone metabolism (PINP, bone TRAP, bAP, Osteocalcin, CTX, NTX, Calcitriol) in blood and urine samples
Data points: days -3 and -1 before bed rest, days 2, 6, 8, 11, and 14 during bed rest, days R2 and R3 after bed rest. Blood sampling was performed after overnight fasting each morning at 7:00 am. 24-hour urine samples were collected for each study day || Changes in cartilage thickness of femur and tibia and concentration of biomarker cartilage oligomeric matrix protein (COMP) in blood samples;

Methods: magnet resonance imaging of the knee joint, biomarkers of cartilage metabolism in blood samples,

Data points magnet resonance imaging: study days -1 before bed rest and R1 after bed rest.

Data points blood samples: study days -3 and -1 before bed rest, study days 2, 6, 8, 11 and 14 during bed rest, study days R2, R3 and R5 after bed rest. Blood sampling was performed at 7:00 am after overnight fasting. || Changes in balance performance; Method: Investigation of the balance performance using the Posturomed device; Data points: day -4 before bed rest and day R 1 after bed rest.

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2004/06/08**
- Target Sample Size: **8**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **35 Years**

Additional Inclusion Criteria

- **healthy male subject**
- **between 18 and 35 years**
- **body weight: 75+/-10 kg**
- **height: 180+/-10 cm**
- **subjects that are willing and have the ability to participate in the whole study**
- **negative skin prick test for sinistrin hypersensitivity**
- **successfully pass the psychological and medical screening**



Exclusion criteria

- Abuse of drugs, medicine or alcohol (regular consumption of more than 20 - 30g alcohol / day)
- Hyperlipidemia
- Adipositas
- kidney disorders
- Participation in another study within 30 days before study onset
- Blood donors in the past three months before the onset of the study
- Smoker
- Diabetes mellitus
- Disposition for keloid
- Rheumatic diseases
- positive skin prick test for sinistrin hypersensitivity
- Bone fractures or severe ligament injuries within one year prior to study onset
- Use of metallic implants
- Shoe size > 44
- No signed consent form before the onset of the experiment
- Every other condition that, in the opinion of the head medical doctor, does not allow a participation in the study

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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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2005/11/30**

Trial Publications, Results and other documents

- Paper **Zange J, Mester J, Heer M, Kluge G, Liphardt AM (2008): 20-Hz whole body vibration training fails to counteract the decrease in leg muscle volume caused by 14 days of 6° head down tilt bed rest. European Journal of Applied Physiology, Jan; 105 (2): 271 ? 7. Epub 2008 Oct 30**
- Paper **Liphardt AM (2008): The Potential of Whole Body Vibration Training during 14-Days of 6°-Head Down Tilt Bed Rest to Counteract Effects on Muscle Performance, Balance and Articular Cartilage. Dissertation, Deutsche Sporthochschule Köln, Köln, Germany.**
- Paper **Liphardt AM, Mündermann A, Koo S, Bäcker N, Andriacchi TP, Zange J, Mester J, Heer M. (2009): Vibration training intervention to maintain cartilage thickness and serum concentrations of cartilage oligometric matrix protein**

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Deutsches Register
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German Clinical
Trials Register

**(COMP) during immobilization. Osteoarthritis Cartilage. Dec;17(12):1598-603.
Epub 2009 Sep 1.**

** 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.*