Trial Description

Title

Relation of MUscular contractions to mechanical STrains in the human tibia during different locomotive activities

Trial Acronym

MUST

URL of the trial

[---]*

Brief Summary in Lay Language

Aim of the study is to determine mechanical deformation of the tibia in the interplay between muscles of the lower leg. A new optical method will be used that will be implemented for the first time in an in vivo study. The experiment will be carried out in five healthy test subjects. Monocortical screws will be inserted into the tibia of the subjects in three locations under local anaesthesia with a short analgosedation if requested. So-called 'marker-clusters' will be attached to the screws. Markers will be captured with a high-resolution camera system. Deformity of the tibial bone under different stresses and movements will be measured. In addition, forces will be measured with force plates (ground-reaction-force, dynamic forces), electrical stimulation of the leg muscles will be measured by electromyography, noise made by the muscles will be recorded by mechanomyography and changes in length will be assessed by ultrasound. The whole procedure of the experiment will be practiced intensively ahead of the in-vivo experiment in dryruns. Here, marker-clusters will be attached to the lower leg with sticky tape to practice motion-capturing. Furthermore bone structure will be assessed with an MRI of the lower leg befor the start of the study for planning of screw insertion. The in-vivo-experiment will be performed in an operation theatre. The Bone pins are frequently used in trauma surgery and will be inserted by an experienced surgeon in an operation theatre under sterile conditions. Markers will be attached to the pins aferwards. The in-vivo experiment includes a variety of exercises that give different strains on the bone. After completion of the experiments, bone-pins will be removed and wounds will be treated according to surgical standards.

Brief Summary in Scientific Language

So far here is no evidence on the interaction of gravitational forces with muscle forces and its influence on deformation of bone. Aim of the study is to determine mechanical deformation of the tibia in the interplay between muscles of the lower leg. A new optical method will be used that will be implemented for the first time in an in vivo study. The experiment will be carried out in five healthy test subjects. Monocortical screws will be inserted into the tibia of the subjects in three locations under local anaesthesia with a short analgosedation if requested. So-called 'marker-clusters' will be attached to the screws. Markers will be captured with a high-resolution camera system. Deformity of the tibial bone under different

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Organizational Data

- DRKS-ID: **DRKS00004207**
- Date of Registration in DRKS: **2012/07/04**
- 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.: **2011306 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- Free text: **Healthy Volunteers**

Interventions/Observational Groups

- Arm 1: **So far here is no evidence on the interaction of gravitational forces with muscle forces and its influence on deformation of bone. Aim of the study is to determine mechanical deformation of the tibia in the interplay between muscles of the lower leg. A new optical method will be used that will be implemented for the first time in an in vivo study. The experiment will be carried out in five healthy test subjects. Monocortical screws will be inserted into the tibia of the subjects in three locations under local anaesthesia with a short analgosedation if requested. So-called 'marker-clusters' will be attached to the screws. Markers will be captured with a high-resolution camera system. Deformity of the tibial bone under different stresses and movements will be**

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Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- 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

Assessment of the influence of muscle force and gravitational force on the deformation of bone (tibia) with a vicon-camerasystem, motion capturing, electromyography, ultrasound und several devices for force measurements.

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutsches Zentrum für Luft- und Raumfahrt, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/05**
- Target Sample Size: **5**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **20 Years**
- Maximum Age: **55 Years**

Additional Inclusion Criteria

- **five male healthy subjects**
- **age between 20 and 55 years**
- **Body mass index (BMI): 20 -30 kg/m2**
- **signed consent form**

Exclusion criteria

• Apart from the PI of the study, Prof. Jörn Rittweger, no further co-workers of DLR or Cologne University Hospital, or financially dependent persons may participate as test subjects
- **corticalis-diameter under 4 mm at site of planned screw insertion**
- **muscle or joint disorders**
- **fractures of the lower extremity in the last 12 months**
- **metall-implants**
- **participation in a different clinical study within 2 months prior to start of study**
- **decreased blood-coagulation**
- **unwanted reactions on local anaesthetic in the past**
- **operations on the tibia in the last 12 months**
- **Any other condition that leads to exclusion from the study in the eyes of the clinical investigator**

Addresses

- **Primary Sponsor**

  Deutsches Zentrum für Luft- und Raumfahrt
  Institut für Luft- und Raumfahrtmedizin
  Weltraumphysiologie
  Mr. Prof. Dr. med. Jörn Rittweger

Primary Sponsor

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■ **Contact for Scientific Queries**

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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 ongoing**
- 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.*