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

Trial Description

Title

Whole Body Vibration Therapy in Intensive Care Patients.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Background: Admission to the intensive care unit (ICU) is particularly associated with a sustained loss of muscle mass, reduced quality of life and increased mortality. Early rehabilitation measures may counteract this process. For this purpose, whole-body vibration (WBV) provides a new approach while the patient is able to remain in bed. This study aims at demonstrating the safety of WBV for patients admitted to the ICU and to compare characteristics of ICU patients and healthy subjects.
Methods: 12 ICU patients and 12 healthy subjects using WBV for the first time while lying in bed were examined. In order to determine safety of the training intensity, the heart rate (HR), oxygen saturation (SaO2) and blood pressure (RR) were measured.
The aim of the study is to show that WBV can also be used as a safe early rehabilitation Treatment in intensive care patients.

Brief Summary in Scientific Language

Scientific Pilot study on the impact of whole body Vibration (WBV) training on the cardiovascular regulation of immobile ICU patients. Numerous studies have shown the positive effect of whole body vibration training in healthy, lung and heart patients. Aim of the study is to demonstrate the safe and acceptable use of the training also in ICU patients.

Organizational Data

- DRKS-ID: **DRKS00009304**
- Date of Registration in DRKS: **2015/09/14**
- 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**

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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **19/15 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- Free text: **intensive care patients**
- Free text: **healthy people**

Interventions/Observational Groups

- Arm 1: **ICU patients: WBV is performed in the patient's bed in supine position. During the study, a training device, type GalileoTM (Novotec Medical, Pforzheim, Germany), was used. The device was attached to the foot of the bed. In order to transmit a sufficient load to the lower limbs, the bed was inclined by 25°.**
  The training was performed in 2 stages. First, the vibrating foot plate was used solely. The training was performed barefoot over duration of three minutes with a frequency of 24Hz and an average intensity of 3 (foot position). During training the knees were slightly inflected. This leads to a decreased conduction of vibrations to the cranium through an increased tension.
  In a second step, a vibrating dumbbell (WBVD) ,mounted at the bed gallow, was added.

- Arm 2: **Healthy control group: WBV is performed in the patient's bed in supine position. During the study, a training device, type GalileoTM (Novotec Medical, Pforzheim, Germany), was used. The device was attached to the foot of the bed. In order to transmit a sufficient load to the lower limbs, the bed was inclined by 25°.**
  The training was performed in 2 stages. First, the vibrating foot plate was used solely. The training was performed barefoot over duration of three minutes with a frequency of 24Hz and an average intensity of 3 (foot position). During training the knees were slightly inflected. This leads to a decreased conduction of vibrations to the cranium through an increased tension.
  In a second step, a vibrating dumbbell (WBVD) ,mounted at the bed gallow, was added.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

We used no classical outcome. The cardiovascular parameters was noticed after the training.

Measurement of cardiovascular parameters (blood pressure, heart rate and oxygen saturation) in:
- before exercise
- Every minute during exercise
- Recovery: 5 minutes after the exercise load

Secondary Outcome

Exercise abort through excessive loading or by the Patient himselve.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Innere Medizin; SP Pneumologie, Marburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/02/23**
- Target Sample Size: **24**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2015/02/23**

Target Sample Size: **24**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. exclusively wake and responsive patients were included
2. All ICU patients who could give a written consent
3. patients who were in no acute life-threatening situation
4. no necrosis or open wounds on the feet

Exclusion criteria

1. intubated and ventilated patients
2. not addressable, comatose patients
3. lack of patient consent

Addresses

- **Primary Sponsor**

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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 complete, follow-up complete**
- Study Closing (LPLV): **2015/04/30**

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.*