

Trial Description

Title

Electromyostimulation induced increase of the cramp treshold frequency - dose-response relationship of a novel prevention concept

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The targeted application of electrically-induced muscle cramps, applied to adapt the muscle to maximum contractions during minimal muscle length, is a promising approach to reduce the cramp susceptibility. This study aims to investigate to what extent the shift in cramp susceptibility is influenced by a dose-response relationship.

Brief Summary in Scientific Language

The focus of this study is to investigate the temporal pattern of the cramp threshold frequency (CTF), the lowest stimulation frequency which elicits a cramp, and blood parameters during two EMS induced interventions of the human musculus gastrocnemius. It is aimed to establish how the CTF changes after one intervention over the course of one week and to what extent a following second intervention further influences muscular adaptations. For that purpose, ten healthy male sport students participate in this study. One calf muscle is electrically stimulated (5 sec on, 10 sec off, 400 µsec pulse width, 30 Hz above the individual CTF, 85 % of the maximally tolerated simulation energy), by means of EMS in a shortened position (plantar flexion), to induce muscle cramps. The calves of five male sport students serve as control.

Organizational Data

- DRKS-ID: **DRKS00005712**
- Date of Registration in DRKS: **2014/02/17**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **107/13 , Ethikkommission der Deutschen Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **R25.2 - Cramp and spasm**
- Free text: **Healthy Volunteers**

Interventions/Observational Groups

- Arm 1: **Stimulation of calf muscles in shortened muscle position by use of electromyostimulation (2 times over a period of 2 weeks).**
- Arm 2: **Control group without stimulation**

Characteristics

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



Primary Outcome

Measuring the minimal electrical stimulation frequency that induces a muscle cramp (CTF) of the m. gastrocnemius medialis before, and daily after the training intervention for one week

Secondary Outcome

Collecting venous blood samples for analysing muscle damage marker

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutsche Sporthochschule Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/03**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

Male sport students between 18 and 40 years

Exclusion criteria

Any injuries of the musculoskeletal system of the lower extremities within the last six months prior to the study and any cardiovascular diseases



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): **2015/03/24**

Trial Publications, Results and other documents

- Abstract **Are Electrically Induced Muscle Cramps Able to Increase the Cramp Threshold Frequency, When Induced Once a Week?**

* 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.