Trial Description

Title

Dose-response relationship of eletrically induced muscle cramps of the musculus gastrocenmius on the cramp threshold frequency (CTF)

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Muscle cramps are a common complain among the general population. Because of their clincical characteristics, sudden, involuntary appearance and a self-dissolving disappearance, it was searched for a method to artificially provoke them. During the last years the electrical stimulation of the muscle's nerve or motor point, was found to be a reliable method to induce cramps. The cramp threshold frequency (CTF), the lowest stimulation frequency, which elicits a cramp in a muscle, is a common parameter in this context. It has been shown that persons with a low CTF are more prone to suffer from frequent cramps, the CTF therefore seems to be a good index of the individual cramp susceptibility. Since to date no effective drug-free treatment approach has been found that eases muscular cramps, this study aims to investigate, if the CTF can be positively influenced by EMS induced muscle cramps in long-term and if a possible change underlies a dose-response relationship. 36 male, healthy sports students participate in this study, they are equally divided into three groups of 12. Depending on the group one week, two weeks or three weeks of intervention are executed. Each of the weeks includes two interventions, separated by three days, during which the calf muscle of one leg is stimulated in a shortened (plantar flexion) position via EMS until it cramps up. Post-intervention and follow-up meassurements of the CTF every 2-3 days are performed to clarify, if the this parameter shows a dependency on the quantity of interventions. Special interest is directed to the question, if a greater number of interventions, results in a longer increase of the CTF above the indvidual baseline (pre-intervention) values.

Brief Summary in Scientific Language

The objective of this study is to investigate the dose-response relationship of EMS induced muscle cramps on the Cramp Threshold Frequency (CTF). 36 male, healthy sports students participate in this study, they are equally divided into three groups of 12 (12 per study arm). Depending on the group one week, two weeks or three weeks of intervention on the musculus gastrocemius medialis and lateralis are executed. The other leg serves as control. Calf muscles are eletrically stimulated in shortened (plantar flexion) position (5sec on, 10sec off, 400µsec pulse width, 30Hz above the individual CTF, 85% of the maximal tolerated stimulation energy), to induce muscle cramps. In order to resolve the temporal changes of the musculus gastrocenmius lateralis CTF, pre-intervention, post-intervention and every 2-3 days follow-up meassurements are performed, until the

indivdual CTF has returned to the pre-intervention baseline value, or until 3 w after the intervention.

Organizational Data

- DRKS-ID: **DRKS00005713**
- Date of Registration in DRKS: **2014/02/19**
- 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.: **107/13 , Ehikkomission der Deutschen Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **During one week, two interventions are executed on the musculus gastrocemius medialis and lateralis of one leg. Calf muscles are eletrically stimulated in shortened (plantar flexion) position (5sec on, 10sec off, 400µsec pulse width, 30Hz above the individual CTF, 85% of the maximal tolerated stimulation energy), to induce muscle cramps. In order to resolve the temporal changes of the musculus gastrocenmius lateralis CTF, pre-intervention, post-intervention and every 2-3 days follow-up meassurements are performed, until the indivdual CTF has returned to the pre-intervention baseline value, or until 3 weeks after the last training session. The other leg serves as control, no intervention is conducted. [This study arm was not accomplished.]**
- Arm 2: **During two weeks, four interventions are executed on the musculus gastrocemius medialis and lateralis of one leg. Calf muscles are eletrically stimulated in shortened (plantar flexion) position (5sec on, 10sec off, 400µsec pulse width, 30Hz above the individual CTF, 85% of the maximal tolerated stimulation energy), to induce muscle cramps. In order to resolve the temporal changes of the musculus gastrocenmius lateralis CTF, pre-intervention, post-intervention and every 2-3 days follow-up meassurements are performed, until the indivdual CTF has returned to the pre-intervention baseline value or until 3 weeks after the last training session. The other leg serves as control, no intervention is conducted.**
- Arm 3: **During three weeks, six interventions are executed on the musculus gastrocemius medialis and lateralis of one leg. Calf muscles are eletrically**

stimulated in shortened (plantar flexion) position (5sec on, 10sec off, 400µsec pulse width, 30Hz above the individual CTF, 85% of the maximal tolerated stimulation energy), to induce muscle cramps. In order to resolve the temporal changes of the musculus gastrocenmius lateralis CTF, pre-intervention, post-intervention and every 2-3 days follow-up meassurements are performed, until the indivdual CTF has returned to the pre-intervention baseline value, or until three weeks after the last training session. The other leg serves as control, no intervention is conducted. [This study arm was not accomplished.]

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Determination of the temporal changes of the Cramp Threshold Frequency, both, during the intervention phase and post-intervention. The follow-up meassurements are performed every 2-3 days until the Cramp Threshold Frequency has returned to its individual pre-test value, or until 3 weeks after the last training session.

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutsche Sporthochschule Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/17**
- Target Sample Size: **36**
- 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 sports students, 18 and 35 years old

Exclusion criteria

Injuries of the musculoskeletal system of the lower extremities during the last six months before commencement of the study, as well as cardiopulmonary illnesses.

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): **2015/06/01**

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.*