

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

## Trial Description

### Title

**Intramuscular Concentrations of Glucose, Lactate, Glutamate, and Glycerol Comparing Chronic Exercise Induced Compartment Syndrome Patients to Controls Before and Following Exercise**

### Trial Acronym

**CECS-MD**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

Pressure measurement with cannulas which are inserted in the muscle is the current standard for diagnostic of chronic compartment syndromes (=muscular overload pain). Recent research, however, questioned the worth of this method. Therefore, there is a need to develop better diagnostic tools.

Microdialysis has been used to analyse markers of cell metabolism.

This project compares patients with chronic exercise induced compartment syndromes of the leg (anterior or deep posterior) to controls by pre- and post-exercise microdialyses. Lactate, glucose, glutamate, and glycerol are examined as markers for energy metabolism and cell damage.

We hypothesized, that microdialysis is able to differentiate patients with chronic exercise induced compartment syndromes of the leg from healthy control persons.

### Brief Summary in Scientific Language

Intracompartmental pressure measurement is the current standard for apporative diagnostic of chronic compartment syndromes. Recent systematic research, however, questioned the validity of this method. Therefore, there is a need to develop more objective tools.

Microdialysis has been used for quantitative analyses of biochemical markers of cell metabolism.

This project compares patients with chronic exercise induced compartment syndromes of the leg (anterior or deep posterior) to controls by pre- and post-exercise microdialyses. Lactate, glucose, glutamate, and glycerol are examined as markers for energy metabolism and cell damage.

We hypothesized, that microdialysis is able to differentiate patients with chronic exercise induced compartment syndromes of the leg from healthy control persons.

### Do you plan to share individual participant data with other researchers?

Yes

## Description IPD sharing plan

**The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.**

## Organizational Data

- DRKS-ID: **DRKS00021589**
- Date of Registration in DRKS: **2020/04/30**
- 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.: **FF33/2009 , Ethikkommission der Landesärztekammer Hessen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **T79.62 - [generalization T79.6: Traumatic ischaemia of muscle]**
- Free text: **Healthy volunteers**

## Interventions/Observational Groups

- Arm 1: **Patients with chronic exercise induced compartment syndromes of the leg (anterior or deep posterior) will undergo pre- and post-exercise microdialyses. Lactate, glucose, glutamate, and glycerol are examined.**
- Arm 2: **Healthy persons will undergo pre- and post-exercise microdialysis of the anterior or deep posterior leg compartment. Lactate, glucose, glutamate, and glycerol are examined**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**

Study Type: **Interventional**

Study Type Non-Interventional: [---]\*

Allocation: **Non-randomized controlled trial**

Blinding: [---]\*

Who is blinded: [---]\*

Control: **Other**

- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Concentration of lactate, glucose, glutamate, and glycerol pre- and post-exercise.**

### Secondary Outcome

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### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- other **Sportmedizinisches Institut, Frankfurt a.M.**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/09/11**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

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Gender: **Both, male and female**

- Minimum Age: **15 Years**
- Maximum Age: **50 Years**

### Additional Inclusion Criteria

#### Patients:

- age > 15 und < 50 years
- intensive sport/running activity
- symptoms at one or two legs
- anterior or deep posterior chronic exercise induced compartment syndrome
- no previous injury/operation of the lower extremities
- typical symptoms more than 12 weeks (spontaneous onset, reproducibly activated by running, increasing pain stops activity, pain over the involved compartment relieved by rest)

#### Asymptomatic group (Control group):

- age >15 and <50 years
- sport activity level comparable to the patients
- anthropometrics comparable to the patients
- no previous injury/operation of the lower extremities
- no chronic compartment syndrome of the leg

### Exclusion criteria

- systemic diseases
- acute or trauma induced onset of symptoms
- duration of the complaints <12 weeks
- abnormal orthopaedic lower extremity findings (malpositions, joint injuries, hypermobility)
- acute and degenerative lumbar spine diseases
- uncertain compliance
- peripheral artery diseases
- venous insufficiency
- lower leg stress injury
- nerve compression
- muscular diseases or muscle injuries

### Addresses

#### ■ 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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- **Institutional budget, no external funding (budget of sponsor/PI)**

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### **Status**

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/08/12**

### **Trial Publications, Results and other documents**

DRKS-ID: **DRKS00021589**

Date of Registration in DRKS: **2020/04/30**

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■ Paper **Microdialysis for chronic exertional compartment syndrome: a pilot study**

\* *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.*