Trial Description

Title

The effects of repetitive peripheral magnetic stimulation in patient with spastic hemiparesis after stroke: A randomized-controlled study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In this study, the effectiveness of repetitive peripheral magnet stimulation (rPMS) is compared to peripheral electrical stimulation.
rPMS improves the functional status of a paretic hand/arm and spasticity after stroke. Since now it is unclear how effective rPMS is.
Patients were randomly assigned to “magnetic stimulation group” or “electrical stimulation group.
The stimulation is applied every day from monday to friday for 3 weeks. In regular intervals assessments were performed for the function of the upper limb and mobility to find out how effective rPMS is.
We hypothesized that rPMS is the more effective stimulation method to improve lost functions in the affected upper limb and the activities of daily living.

Brief Summary in Scientific Language

Repetitive peripheral magnetic stimulation (rPMS) is a stimulation method with strong and rapidly changed magnetic fields that's applicated on a muscle to produce repetitive muscle contractions.
The first rPMS trials by patients after stroke were performed in the 90s by the research group by Albrecht Struppler. These first trials indicated an improvement of voluntary activity, spasticity and perception after rPMS.
In this randomized-controlled trial the effect of rPMS will be examined in patients after stroke. The patients are randomly assigned in the intervention group(magnetic stimulation) and the control group (electrical stimulation). The intervention /controllintervention be applied daily (mon-fri) over three weeks.
To investigate the short- and long-term effects standardized the assessments will be evaluated at different times.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00007899**
- Date of Registration in DRKS: **2015/03/24**
- 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.: **4147-07/14 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- ICD10: **I60-I69 - Cerebrovascular diseases**
- ICD10: **G81.1 - Spastic hemiplegia**

Interventions/Observational Groups

- Arm 1: **repetitive peripheral magnetic stimulation (rPMS) (interventiongroup):**

  The stimulation is 15 minutes daily for three weeks with a total of 15 sessions. The stimulation intensity is adjusted individually for each patient, so that a joint movement resulting from the muscle contraction.

  Muscles of the upper arm and forearm are stimulated with a butterfly coil;
  The patient takes a sitting position with raised feet in the wheelchair or on a chair with backrest;
  The arm is placed to be stimulated or maintained by the therapist

  magnetic stimulator: Magstim Rapid²

  Instruction:
  Patients are asked to relax and observe their arm

- Arm 2: **peripheral electrical stimulation (controlgroup):**

  The stimulation is 15 minutes daily for three weeks with a total of 15 sessions. The stimulation intensity is adjusted individually for each patient, so that a

joint movement resulting from the muscle contraction.

**Muscles of the upper arm and forearm are stimulated with electrodes;
The patient takes a sitting position with raised feet in the wheelchair or on a chair with backrest;
The arm is placed to be stimulated or maintained by the therapist;**

Electrical device: wellcare digi stim

Instruction: Patients are asked to relax and observe their arm

Characteristics

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

Primary Outcome

The primary outcome is the Fugl-Meyer Test of the upper extremity, a test that evaluated the function of the affected upper extremity. This test will be performed directly after the end of the three weeks intervention-/controllintervention.

Secondary Outcome

The secondary outcome is determined with a questionnaire, the Katz Index of Independence Activities of daily living (ADL). That questionnaire aims to identify the dependence in the performance in the activities of daily living and will be performed six months after the end of the intervention /controllintervention.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Moritz Klinik , Bad Klosterlausnitz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/15**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

subacute stroke (incident not longer than six months back)
spastic hemiparesis of the upper limb (at least modified ashworth scale 1)
a slight function in the fingers or hand (at least 1 point in the Fugl-Meyer-test in subscore C)

Exclusion criteria

Epilepsy,
implantated metal in the stimulation area
implantated medical devices
dysfunctional speech comprehension
pregnancy

Addresses

- **Primary Sponsor**

  Moritz Klinik Bad Klosterlausnitz
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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 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.*