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

Trial Description

Title

The effects of repetitive peripheral magnetic stimulation on motor function and spasticity in patients with hemiparesis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

A damage to motor pathways due to a stroke or a traumatic disorder can lead to an increase in muscle tone culminating in spasticity. An increase in muscle tone usually occures in the muscles responsible for arm flexion or leg Extension of the affected paretic body side. Within this study a magnetic stimulation of the paretic muscles will be done. With repetitive magnetic Impulses, applied via a magnetic coil, the muscles will be stimulated without any pain.
The study intervention will be applied for 2 weeks on 10 days twice a day. The patients' function will be assessed before and after this period. A follow up will be performed after an additional 2-week period. This is a randomized controlled trial, i.e., a patient is either allocated to a verum magnetic stimulation or to a sham stimulation. Both Groups will receive an additional occupational therapy.

Brief Summary in Scientific Language

Pyramidal and extrapyramidal tract lesions lead to an increased muscle tone after several weeks or months as a consequence of stroke or trauma, often in combination with disturbance of proprioceptive input. The aim of this study was to reduce pathological muscle tone and to stimulate cortical reorganization using repetitive peripheral magnetic stimulation (rpMS), by generating repetitive contraction-relaxation cycles and enhancing proprioceptive input from the affected extremity. Patients were randomized to rpMS or sham (placebo) stimulation. We used rpMS (P-Stim 160) consisting of 5000 stimuli at a stimulation frequency of 25 Hz. Intensity was individually set to 10 % above the level that evoked a wrist or elbow movement. Stimuli were distributed consistently among extensors and flexors of the upper and lower arm.
Treatment sessions (20 min rpMS or sham and subsequently 20 min of occupational therapy) were scheduled two times per day over a 2 week period. Therapists, blinded for treatment allocation, assessed each patient using the Tardieu and the Fugl-Meyer Assessment before and after the treatment period and after a follow-up period of 2 weeks, i.e. 3 times. Additionally a Tardieu assessment was done after the 1st session and before the 3rd session to examine short-term effects.

Organizational Data

- DRKS-ID: **DRKS00000798**
- Date of Registration in DRKS: **2018/03/05**
- 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.: **07021 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

Health condition or Problem studied

- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **S06.9 - Intracranial injury, unspecified**

Interventions/Observational Groups

- Arm 1: **Treatment: 20-minute therapy sessions of repetitive peripheral magnetic stimulation (rpMS) plus an additional 20 minutes of occupational therapy, 2 times a day, 5 times a week, for 2 weeks.**
- Arm 2: **sham stimulation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, assessor**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary outcome parameter is the function and spasticity of the paretic upper extremity. The Fugl-Mayer assessment is used to assess function, and the Tardieu scale to assess spasticity.
Both scales will be assessed before therapy, at the end of the 2-week treatment period, and 2 weeks after study treatment. Additionally the Tardieu Scale will be assessed after the first and before the third therapy session to determine any short-term effects.

Secondary Outcome

As secondary outcome the independance in activities of daily living, depression, and the tolerance to the stimulation will be documented. These aspects will assessed by means of the Barthel Index, the 7-item Hamilton Depression Scale, and a self-report questionnaire. Muscle activity of the paretic upper extremity will be measured with electromyography (EMG). All Parameters will be collected before and after the Intervention period, and 2 weeks after study treatment.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/04/21**
- Target Sample Size: **44**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

• hemiparesis after stroke or traumatic brain injury
• grade 1 to 3 on Tardieu scale

Exclusion criteria

• co-morbidity with other degenerative diseases
• implanted medical devices, i.e.
o cardiac pacemaker
o Cochlea- implant
• pregnancy
• metal implants (head and/or stimulation area)
• instabile fractures within stimulation area
• pathological intracraniel pressure

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): **2008/05/28**

Trial Publications, Results and other documents

■ Abstract **Publikation der Studienergebnisse**

** 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.*