Trial Description

Title

Repetitive peripheral magnetic stimulation (rPMS) for the treatment of muscular tension in patients with depression

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Depressive patients often additionally suffer from increased muscular tension in their neck and back muscles. We want to examine, to what extent this muscular tension can be eased and whether maybe even depressive symptoms can be improved by treatment with repetitive magnetic stimulation. Treatment with repetitive magnetic stimulation will be compared with sham treatment using very low, non-effective magnetic pulses.

Brief Summary in Scientific Language

Repetitive peripheral magnetic stimulation is evaluated systematically since the early 1990s. In principle, rPMS is used either to directly stimulate peripheral nerves or muscles. rTMS has been studied in the context of stroke rehabilitation, in treatment of complex regional pain syndrome (CRPS), and pain as a result of plexus as well as for treatment of spasticity before.
Depressive disorders are a common disease. Despite a large array of effective pharmacological and psychotherapeutic treatment approaches, its treatment still remains a challenge. In addition to the common symptoms of depression like depressed mood, loss of interest and pleasure many patients also complain physical impairments.
Pain, especially back pain and muscle tensness, as well as heart disease or gastrointestinal complaints are often reported. To date there are no studies reagarding the efficacy of rPMS in depressed patients suffering from muscular tensness.
We intend to investigate whether peripheral repetitive magnetic stimulation can improve muscular tension states and how such an improvement affects depressive symptoms.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005078**
- Date of Registration in DRKS: **2013/07/03**
- 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.: **12-101-0229 , Ethikkommission an der Universität Regensburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F32 - Depressive episode**
- ICD10: **F31.3 - Bipolar affective disorder, current episode mild or moderate depression**
- ICD10: **F31.4 - Bipolar affective disorder, current episode severe depression without psychotic symptoms**
- ICD10: **F31.5 - Bipolar affective disorder, current episode severe depression with psychotic symptoms**

Interventions/Observational Groups

- Arm 1: **Verum rPMS will be given for 10 days (Monday to Friday). The duration of a single treatment session is about 10 minutes and is divided into a warm-up phase (stimulation parameters: stimulation intensity 15-20% of maximum power, 5 Hz, 15 pulses per train, 15 trains, inter-train-interval 2 s) and a subsequent treatment phase (stimulation parameters: stimulation intensity about 3-5% more than in warm-up phase, 15 Hz, 45 pulses per train, 15 trains, inter-train interval 2 s). Warm-up and treatment phases differ only in terms of the strength of the magnetic pulse to cause only slight muscle twitching but no movement during the warm-up phase while in the treatment phase, slight muscle movements should be visible. The intensity of treatment should be selected in any case in a way that stimulation is not perceived as painful.**
- Arm 2: **Sham rPMS for 10 days (Monday to Friday). Sham-treatment is identical to verum treatment, except that the power of stimulation is limited to 5-10%. By this means perception of the magnetic pulse should be possible, but no relevant muscle stimulation should be attained. A noise generator is used to adapt the lower stimulation sound of the sham treatment to the verum**

treatment.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **patient/subject, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Neck pain symptoms, measured by a standardized sef-rating scale (Neck pain and disability scale, NPAD) before and after treatment

Secondary Outcome

depressive symptoms, measured by standardized self and extraneous rating scales (Hamilton Depressions Scale, HAMD und Beck Depression Inventory, BDI) before and after treatment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Sozialstiftung Bamberg, Klinik für Psychiatrie, Psychosomatik und Psychotherapie, Bamberg**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie, Regensburg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/08/01**
-

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2013/08/01**

Target Sample Size: **40**

- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients suffering from a major depressive episode in the context of a uni-or bipolar disorder (ICD-10: F32.x, F33.x or F31.3-5);
Subjectively reported muscular tension in the neck and shoulder muscles of the back of at least moderate intensity (NPAD total value> = 40 points)

Exclusion criteria

Severe osteoporosis;
Known muscle diseases (eg muscular dystrophies, atrophies, etc.) or neurodegenerative diseases (eg, amyotrophic lateral sclerosis); osteosynthesis or metal parts in the regions to be treated with rPMS;
Implanted pump systems, pacemakers, etc.;
pregnancy

Addresses

- **Primary Sponsor**

Sozialstiftung Bamberg
Klinik für Psychiatrie, Psychosomatik und Psychotherapie
Mr. Prof. Göran Hajak
St.-Getreu-Str. 18
96049 Bamberg
Germany

Telephone: **0951 50321001**
Fax: **0951 50321009**
E-mail: **goeran.hajak at sozialstiftung-bamberg.de**
URL: **www.sozialstiftung-bamberg.de**

- **Contact for Scientific Queries**

Contact for Scientific Queries

Sozialstiftung Bamberg
Klinik für Psychiatrie, Psychotherapie und Psychosomatik
Mr. Dr. Wolfgang Trapp
St. Getreu-Str. 18
96049 Bamberg
Germany

Telephone: **0951 50326123**
Fax: **0951 50321009**
E-mail: **wolfgang.trapp at sozialstiftung-bamberg.de**
URL: **www.sozialstiftung-bamberg.de**

- **Contact for Public Queries**

Sozialstiftung Bamberg
Klinik für Psychiatrie, Psychosomatik und Psychotherapie
Mr. Prof. Göran Hajak
St.-Getreu-Str. 18
96049 Bamberg
Germany

Telephone: **0951 50321001**
Fax: **0951 50321009**
E-mail: **goeran.hajak at sozialstiftung-bamberg.de**
URL: **www.sozialstiftung-bamberg.de**

Sources of Monetary or Material Support

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

Sozialstiftung Bamberg
Klinik für Psychiatrie, Psychosomatik und Psychotherapie
St.-Getreu-Straße 18
96049 Bamberg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*