Trial Description

Title

Comparison of the Brainstim tDCS stimulator versus the neuroconn tDCS stimulator in terms of effiency and comfort

Trial Acronym

Brainstim versus neuroconn

URL of the trial

http://www.klinikum.uni-muenchen.de/Klinik-und-Poliklinik-fuer-Psychiatrie-und-Psychotherapie/de/forschung/tms/schwerpunkte/tdcs.html

Brief Summary in Lay Language

transcranial direct current stimulation is a novel treatment option for various neurologic and psychiatric disorders. With electric stimulators, direct current is applied to the brain. In this trial, we compare the Italian Brainstim stimulator to the German neuroconn stimulator in terms of efficiency and comfort. The Trial is randomized and single-blinded. Outcome is measured by questionnaires and EEG measures.
Both stimulators are CE-certified.

Brief Summary in Scientific Language

singel blinded, randomized cross-over study to compare the Brainstim and the neuroconn tDCS stimulator. Outcome measures are made by comfort rating questionnaires and LORETA EEG measures. There are four conditions: Italian versus German stimulator, both active and sham stimulation.

Organizational Data

- DRKS-ID: **DRKS00003602**
- Date of Registration in DRKS: **2012/03/09**
- 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.: **402-10 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- Free text: **healthy volunteers**

Interventions/Observational Groups

- Arm 1: **cephalic stimulation with the neuroconn stimulator, active condition**
- Arm 2: **cephalic stimulation with the neuroconn stimulator, sham condition**
- Arm 3: **cephalic stimulation with the brainstim stimulator, active condition**
- Arm 4: **cephalic stimulation with the brainstim stimulator, sham condition**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Placebo, Active control**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

End point is the completion of four different treatment conditions for comparison of comfort and efficiency due to the single measures. Stimulations take place with a minimum 24 h interval, measures are immediately after stimulation. Each volunteer has to assess uncomfortable side effects of the stimulation with the Comfort Rating Questionnaire. Additionally EEG recording is performed at baseline before first stimulation and after each stimulation. Aim is to show similar effects of both stimulators in terms of comfortability of active and sham stimulation and the documentation of the same activation of deep brain regions by both stimulators, measured by EEG-LORETA.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Psychiatrische Klinik, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/01**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

healthy subjects

Exclusion criteria

neurologic, psychiatric, internal, dermatologic disorders, obesity.

Addresses

- **Primary Sponsor**

  Klinik für Psychiatrie, Psychotherapie und Psychosomatik
  Mr. Dr. Ulrich Palm
  Nußbaumstr. 7
  80336 München
  Germany

  Telephone: **089/5160-5511**

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Germany

Telephone: **089/5160-5511**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Psychiatrische Klinik
Mr. Dr. Ulrich Palm
Nußbaumstr. 7
80336 München
Germany

Telephone: **089/5160-5511**
Fax: **[---]***
E-mail: **ulrich.palm at med.uni-muenchen.de**
URL: **http://www.klinikum.uni-muenchen.de/Klinik-und-Poliklinik-fuer-Psychiatrie-und-Psychotherapie/de/forschung/tms/schwerpunkte/tdcs.html**

■ **Contact for Public Queries**

Klinik für Psychiatrie, Psychotherapie und Psychosomatik
Mr. Dr. Ulrich Palm
Nußbaumstr. 7
80336 München
Germany

Telephone: **089/5160-5511**
Fax: **[---]***
E-mail: **ulrich.palm at med.uni-muenchen.de**
URL: **[---]***

Sources of Monetary or Material Support

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

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/01/30**

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.*