Trial Description

Title

Treatment of depression during pregnancy with transcranial direct current stimulation

Trial Acronym

DeSteK

URL of the trial

[---]*

Brief Summary in Lay Language

Depressive disorders during pregnancy are risk factors for child and mother and are currently treated with antidpressant medication. However there is a risk of teratogeneity and malformations under antidepressant treatment. Transcranial direct current stimulation is a tool for modulating neuronal activity in the brain and provides antidepressant efficacy. Systemic side effects for child and mother are not likely due to the focality of the stimulation to the brain. In this study depressed pregnant women are treated with twice-daily stimulation for two weeks. Antidepressant medication will not be given.

Brief Summary in Scientific Language

transcranial direct current stimulation (tDCS) is a non-invasive tool for the modulation of neuronal activity and shwos antidepressant efficacy when applied to the prefrontal cortex. Several syfety studies showed that tDCS has no systemic side effects. For this reason, application for depression in pregnancy is possible and reasonable. In this study, depressed pregenant women reluctant to pharmacological treatment will be given a series of 2 mA/30 min tDCS (F3/F4) twice daily for two weeks.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008537**
- Date of Registration in DRKS: **2015/05/08**

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- 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.: **47-15 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F31.4 - Bipolar affective disorder, current episode severe depression without psychotic symptoms**

Interventions/Observational Groups

- Arm 1: **acitve tDCS; 2 mA; 2x30 min per day; anode: F3; cathode: F4; total treatments: 20; duration: 14 days.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

With application of the 20th stimulation: performance of rating instuments: Hamilton Depression Rating Scale-21; Beck Depression Inventory; WHO-Qualitiy of Life Bref; CGI; GAF; Trail Making Test A/B.

Secondary Outcome

With application of the 20th stimulation: Performance of the Comfort Rating Questionnaire (CRQ): proof of a stimulation without side effects.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **LMU, Klinik für Psychiatrie, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/13**
- Target Sample Size: **10**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **10 Weeks of pregnancy**
- Maximum Age: **35 Weeks of pregnancy**

Additional Inclusion Criteria

current pregnancy; Age 18-45; diagnosis of a depressive syndrome without etiologic conclusion; HAMD score minimum 15; normal gynecologic-obstetric and fetal examination; ability to give informed consent.

Exclusion criteria

lack of informed consent; other severe psychiatric disorders; suicidality; Treatment with psychopharmacologic drugs; brain or skull trauma in anamnesis;

structural brain damage; Epilepsy; electronic implants in skull or neck; malignant diseases; severe skin or infectious diseases; heart or lung diseases; fetal malformations; pregnancy at risk.

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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URL: **[---]***

Status

- Recruitment Status: **Enrolling by invitation**
- 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.*