Trial Description

Title

Evaluation of striatal dopamine transporter availability in patients with therapyresistent major depression, treated by sleep deprivation and electroconvulsive therapy

Trial Acronym

[---]*

URL of the trial

http://entfällt

Brief Summary in Lay Language

Electroconvlusive therapy (ECT) and sleep deprivation (SD) are valuable antidepressive treatments. However, their antidepressive mechanisms are poorly understood. Often its difficult to predict individual efficacy of the treatment or to plan the duration and fequency of ECT course. Here an objective biomarker would be helpful.
The subject of our study is to better understand the changes that ECT and SE might induce in the brain, e.g. transmitter changes. Therefore we plan to investigate the dopamine transporter in the brain by nuclear medicine technique and in the blood. In parallel depressive symptoms and cognitive function of the patients will be evaluated.

Brief Summary in Scientific Language

Major depression is the most frequent psychiatric disease in adults.

Antidepressant drugs in combination with psychotherapy are most commonly used for treatment of major depression. However, a significant fraction of patients (up to 50%) (,) turn out to be therapy refractory so that somatic treatment approaches are chosen in accordance with national guidelines. Most notably, these include electroconvulsive therapy (ECT) and sleep deprivation (SD) ( ).

Although ECT and SD have been used as very effective treatment in the majority of patients for over 80 years, underlying mechanisms of actions are poorly understood. Against this background, the major aims of the present study are:

-to investigate the effect of SD and ECT on DAT availability in patients with major depression, which will contribute to our understanding of mechanisms of action of

Finally, data from patients with major depression will be compared with data from age- and gender-matched healthy controls to identify possible disease-specific, ECT- and SD- unrelated parameter changes (DAT availability, in particular) and to investigate in how far ECT and SD lead to a normalization thereof.

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: **DRKS00003134**
- Date of Registration in DRKS: **2011/06/15**
- 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.: **184/11 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F33.2 - Recurrent depressive disorder, current episode severe without psychotic symptoms**
- ICD10: **F33.3 - Recurrent depressive disorder, current episode severe with psychotic symptoms**

Interventions/Observational Groups

- Arm 1: **sleep deprivation one night, after a break of 7 days electroconvulsive therapy starts for a course of 6 weeks, 2 times weekly; treatment in patient with major depression**
- Arm 2: **healthy controls without intervention**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Comparison of striatal DAT availability in patients with major depression at baseline, after one night of total SD and after 6 weeks of ECT assessed with [123I]FP-CIT SPECT

Secondary Outcome

- comparison of DAT availability in major depression with DAT availability of healthy controls at baseline, after one night of total SD and after 6 weeks of ECT with [123I]FP-CIT-SPECT

- correlation of DAT availability in major depression and healthy controls with DAT availability of lymphcytes at baseline, after one night of total SD and after 6 weeks of ECTby semiquantitative PCR from blood samples

- comparison of clinical parameters. psychiatric examination (especially affectivity and cognitive function) in patients at baseline, after one night of total SD and after 6 weeks of ECTby standardized clincial tests (HMD; BDI; congitive test battery).

- correlation of clinical parameters with striatal and lymphocatic DATavailability in major depression at baseline, after one night of total SD and after 6 weeks of ECT

-correlation of biomarkers (polymorphisms of DAT-gen, of adenosindesaminase-gen by PCR from blood samples, saliva cortisol) with striatal und lymphcytic DAT-availability

-correlation of clinical parameters with above mentioned biomarkers.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/01**
- Target Sample Size: **24**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

a) written informed consent
b) age 18 to 80 years
c) patients: diagnosis of major depression according to ICD10 criteria AND refractory to at least two preceding evidence-based therapies, scheduled for SD and ECT
d) cerebral MRI without structural changes possibly responsible for an affective disorder

Exclusion criteria

e) pregnancy (excluded by pregnancy test in fertile women) and lactation

syndrome, epilepsy, cerebrovascular disease)

m) any malignant disease with possible impact on life expectancy

n) severe cardiovascular disease e.g. Angina, chronic heart failure, arrhythmia)

o) any severe internal disease with possible impact on life expectancy (e.g., CAD, uncontrolled hypertension, liver or kidney disease, etc.)

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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  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.*