Trial Description

Title

Dysfunctional neuronal networks in alcoholism: Utilizing translational neuroimaging to identify altered brain connectivity and treatment efficacy predictors

Trial Acronym

Transalc

URL of the trial

http://www.transalc.eu

Brief Summary in Lay Language

**There is some evidence that the connections between different brain areas are affected by alcohol dependence. Therefore we want to investigate the differences between alchol- dependet patientes and healthy controll subjects.
With MRI (Magnet Resonance Imaging) we will make brain images using two different techniques: First Diffusions-Tensor-Imaging (DTI) to see how well and in which direction the water inclosed in the neuronal brain bundles moves. This shows whether the function of the brain bundles and the flow of information between brain areas is efficient. Second we will make a Resting-State MRI. This is to investigate the communication of brain areas without doing concentrated exercises but beeing at rest. If two areas show activity at the same time we can conclude that they have a connection.**

Brief Summary in Scientific Language

Alcoholism is a common psychiatric disorder with largely unmet treatment needs. Excellent animal models for this disorder have put forward a number of promising molecular targets for medication development. Yet, clinical trials aimed at exploiting this potential often fall short of expectations. We aim to improve the predictive validity of animal tests by means of functional connectivity analysis using magnetic resonance imaging (MRI) to identify brain response patterns to pharmacotherapy that are comparable between patients and animal models of alcoholism. To this end we have formed an international consortium with highly complementary expertise in the field of alcoholism and neuroimaging research. This project will reveal alcoholism specific connectivity maps and knowledge of their modification by clinical reference compounds, i.e. acamprosate and naltrexone, in humans and animals. Based on this information we expect to predict better the effects of experimental drugs proposed for treatment of alcoholism in human patients.

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

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003357**
- Date of Registration in DRKS: **2011/11/29**
- 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.: **2010-348N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F10.2 - Mental and behavioural disorders due to use of alcohol; Dependence syndrome**

Interventions/Observational Groups

- Arm 1: **alcohol dependent patients with anticraving medication (Naltrexone or Acamprosate)**
- Arm 2: **alcohol dependent patients without anticraving medication**
- Arm 3: **healthy controlls**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***

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- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To determine differences in functional connectivity between alcohol addicted patients and healthy controls using rsfMRI and DTI

Secondary Outcome

To determine differences in functional connectivity between alcohol addicted patients treated with Naltrexone or Acamprosate vs. alcohol addicted patients without medication using rsfMRI and DTI

Countries of recruitment

- DE **Germany**
- CA **Canada**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/01**
- Target Sample Size: **270**
- Monocenter/Multicenter trial: **Multicenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/12/01**

Target Sample Size: **270**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

**alcohol dependence (DSM IV; ICD 10) and
average84g of pure alcohol per day during the last 90 days**

Exclusion criteria

other Axis 1 psychiatric diagnoses than alcohol- or nicotine-dependence in the last 12 months, common exclusion criteria for MRI, positive urine drug screen, severe medical illness and history of brain injury

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- 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.*