Trial Description

Title

The adminstration of ear acupuncture according to the NADA protocol to patients with alcohol dependende

Trial Acronym

acupuncture001

URL of the trial

[---]*

Brief Summary in Lay Language

This study aims to investigate the effects of ear acupuncture according to the NADA protocol on craving, treatment adherence, anxiety, depression and psychophysiological parameters in patients alcohocol who are presently abstinent from alcohol. For this purpose 72 inpatients of a rehabilitation clinic will be included.
The patients will be randomized into three study groups: patients assigned to group 1 will receive ear acupuncture according to the NADA protocol. Patients of group two will receive placebo (sham) acupuncture and patients of group three will not receive any acupuncture.

Brief Summary in Scientific Language

The patients included will be randomized into three study groups: patients assigned to group 1 will receive ear acupuncture according to the NADA protocol. Patients of group two will receive placebo (sham) acupuncture and patients of group three will not receive any acupuncture. Measurements of psychometric and psychophysiological parameters will be performed at repeated time points prior to the six week acupuncture treatment phase and up to 4 weeks afterwards. Identical measurements will be conducted in patients who do not receive acupuncture at the same time points. All participants will receive multimodal postacute inpatient treatment. Abstinence from alcohol will be confirmed by alcohol breathing tests (Alkomattests).

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005474**
- Date of Registration in DRKS: **2013/11/26**
- 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.: **EK353092013 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

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: **NADA ear acupuncture (20 sessions over 6 weeks)**
- Arm 2: **placebo (sham) acupuncture (20 sessions over 6 weeks)**
- Arm 3: **control (without acupuncture)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Placebo, No treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

heart rate variabilty (analysis of ECG and pulse wave)
3 time points of measurement: before start of first treatment and on the last

treatment day as well as four weeks afterwards

Secondary Outcome

craving, anxiety, depression, psychic symptom load, relaxation, skin conductance, skin blood flow
Psychometric questionaires, skin resistance, photopletysmography
3 time points of measurement: before start of first treatment and on the last treatment day as well as four weeks afterwards

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Fachklinik, Dresden**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/09**
- Target Sample Size: **72**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **72 Years**

Additional Inclusion Criteria

alcohol dependence, staying abstinent from alcohol for at least five days

Exclusion criteria

oral administration of a beta-blocker within 14 days prior to study begin, oral administration of antidepressants within three months prior to study begin, oral administration of anticoagulants within 14 days prior to study begin, diabetis mellitus, coronary heart disease, heart failure, dementia, schizophrenia, major depression or bipolar disorder, drug addiction, known metal allergy

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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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.*