Trial Description

Title

Development and validation of a hard- and software based procedure for dementia diagnose, monitoring and image documentation obtained by the creative painting and drawing pocess of patient images

Trial Acronym

ZIM-Project

URL of the trial

[---]*

Brief Summary in Lay Language

In this study we develop an easily applicable digital screening method with the aim of being able to distinguish between an early stage of Alzheimer´s dementia and a normal age-related cognition weakness.

Brief Summary in Scientific Language

In the dementia diagnostics many tests in the field of analyzing handwritten drawings, for example the clock drawing test, are well established. However there are restrictions regarding the evaluation of the production of the drawing. Ductus, holding and releasing of the pen and drawing speed cannot be recorded and measured, but which provide important evidences about the extent of the cognitive impairment. The idea of this study is to use modern capturing devices such as tablets to allow the detailed documentation of the diagnostic criteria of the patient´s drawing process. This study deals with the development and validation of a digital drawing device in order to be able to gather a variety of art therapeutic relevant fingerprints in patient images and to evaluate them for diagnosis. The objective is to use this hard- and software based screening method in the early diagnostics of Alzheimer´s disease.

Organizational Data

- DRKS-ID: **DRKS00008840**
- Date of Registration in DRKS: **2015/07/29**
- 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.: **199/2015BO1 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F06.7 - Mild cognitive disorder**
- ICD10: **F01 - Vascular dementia**

Interventions/Observational Groups

- Arm 1: **Neuropsychological Test Battery (CERAD plus; Memory Clinic Basel)**
  Depression Screening (affective state),
  Creating drawings on the tablet

Characteristics

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

Primary Outcome

early diagnosis of dementia,
positive predictive value mind. 90%

Secondary Outcome

capable of overcoming shortcomings
in current medical diagnostics, differential diagnosis of chronic depression, a

completion of medical tests, a simple status investigation and a competent monitoring, measurement of the variation of the state of mind on a given day

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Memory Clinic, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/01**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **49 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**physically able to meet the testing requirements,
sufficient language ability (German),
sufficient (corrected) normal visual acuity,
sufficient (corrected) hearing**

Exclusion criteria

**Pregnant and lactating women.
Persons who are held in an institutional custody due to cort order or administrative order.
Participants with physical disabilities that affect his or her ability to carry out the required tasks.**

Addresses

■ **Primary Sponsor**

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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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Tschaikowskistraße 49
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13156 Berlin
Germany

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

Status

- Recruitment Status: **Recruiting suspended on temporary hold**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Paper **Müller, S., Preische, O., Heymann, P., Elbing, U., and Laske, C. “Diagnostic Value of a Tablet-Based Drawing Task for Discrimination of Patients in the Early Course of Alzheimer’s Disease from Healthy Individuals.” Journal of Alzheimer’s Disease 55.4 (2016): 1463–1469. CrossRef. Web.**
- Paper **Müller, S., Preische, O., Heymann, P., Elbing, U. and Laske, C. "Increased Diagnostic Accuracy of Digital vs. Conventional Clock Drawing Test for Discrimination of Patients in the Early Course of Alzheimer’s Disease from Cognitively Healthy Individuals" Front Aging Neurosci 9: 101 (2017): doi: 10.3389/fnagi.2017.00101**

** 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.*