



Trial Description

Title

Transfer of plasma samples for assay development in the patent application "New approaches to Alzheimer's diagnosis"

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In the above study we collect blood samples from healthy and diseased people aged 50 years and older. This will only be done when there is no contraindication for taking a blood sample and a informed consent was signed. The blood samples will be anonymised after collection. The samples will be used for testing a new method of investigation. This new method will be used in the future in the context of early Alzheimer's diagnosis.

Brief Summary in Scientific Language

This study uses anonymised blood samples from healthy and diseased subjects to check a new method for diagnosis of Alzheimer Dementia. The new research method is to be used in the future in the diagnosis of Alzheimer Dementia.

Organizational Data

- DRKS-ID: **DRKS00004628**
- Date of Registration in DRKS: **2013/01/10**
- 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.: **12-5300-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **F00 - Dementia in Alzheimer's disease**

Interventions/Observational Groups

- Arm 1: **Healthy and diseased subjects receive a blood draw. The samples will be anonymised and used for an assay development.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- 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

Development of immunological tests for human blood plasma for determining the concentration of A β (1-40) and A β (1-42) and for comparison.

Secondary Outcome

/

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **Medical Center LVR-Klinikum Essen, Kliniken und Institut der Universität Duisburg-Essen, Essen**



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/15**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- a) The study participant can understand the situation, the clinical trial and the consequences of taking part at the clinical trial and the participant is in position to give the consent;**
- b) the study participants signed and personally dated the consent before any test-specific action is taken;**
- c) age of the study participant is 50 years or older.**

Exclusion criteria

Health concerns against sampling blood as study-specific measure.

Addresses

■ Primary Sponsor

**LVR-Klinikum Essen, Kliniken und Institut der Universität Duisburg-Essen
Mr. Prof. Dr. Jens Wiltfang
Altendorfer Str. 97-101
45127 Essen
Germany**

Telephone: **0201-7227-202**

Fax: **0201-7227-300**

E-mail: **jens.wiltfang at uni-due.de**

URL: **http://www.rk-essen.lvr.de/**

■ Contact for Scientific Queries

**LVR-Klinikum Essen, Kliniken und Insitut der Universität Duisburg-Essen
Mr. Prof. Dr. Jens Wiltfang**

Contact for Scientific Queries

LVR-Klinikum Essen, Kliniken und Insitut der Universität Duisburg-Essen

Mr. Prof. Dr. Jens Wiltfang

Altendorfer Str. 97-101

45127 Essen

Germany

Telephone: **0201-7227 202**

Fax: **0201-7227 300**

E-mail: **jens.wiltfang at uni-due.de**

URL: **http://www.rk-essen.lvr.de/**

■ Contact for Public Queries

LVR-Klinikum Essen, Kliniken und Institut der Universität Duisburg-Essen

Ms. Sinja Henrike Meyer

Wickenburgstr. 23

45147 Essen

Germany

Telephone: **0201-8707 220**

Fax: **0201-8707 104**

E-mail: **sinja.meyer at uni-due.de**

URL: **http://www.rk-essen.lvr.de/**

Sources of Monetary or Material Support

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

LVR-Klinikum Essen, Kliniken und Institut der Universität Duisburg-Essen

Mr. Prof. Dr. Jens Wiltfang

Altendorfer Str. 97-101

45127 Essen

Germany

Telephone: **0201-7227 202**

Fax: **0201-7227 300**

E-mail: **jens.wiltfang at uni-due.de**

URL: **http://www.rk-essen.lvr.de/**

Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2013/09/30**

DRKS-ID: **DRKS00004628**

Date of Registration in DRKS: **2013/01/10**

Date of Registration in Partner Registry or other Primary Registry: [---]*

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.*