# Cross-sectional characterisation of elderly using the NeuroCart.

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Main objectives:To determine differences in NeuroCart profiles in different sub-groups based on cognitive testing and CSF biomarker profiling (i.e. cognitively normal, pre-symptomatic AD, prodromal AD, MCI, mild AD).To characterize a cohort of...

**Ethical review** Not approved **Status** Will not start

Health condition type Neurological disorders congenital

**Study type** Observational invasive

# **Summary**

#### ID

NL-OMON43551

#### Source

**ToetsingOnline** 

#### **Brief title**

Cross-sectional NeuroCart study in elderly.

#### **Condition**

Neurological disorders congenital

#### **Synonym**

Alzheimer's disease, dementia

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Centre for Human Drug Research **Source(s) of monetary or material Support:** CHDR

## Intervention

Keyword: elderly, Neurocart

### **Outcome measures**

Primary outcome
NeuroCart assessments
* Adaptive tracking test;
* Visual Verbal Learning Test (VVLT);
* Milner Maze test;
* Visual Analogue Scales according to Bond and Lader (VAS-BL); alertness, mood
and calmness;
* Face encoding and recognition test;
* N-back test;
* Sustained Attention to Response test (SART);
* 21 leads electroencephalogram (EEG)
* Event related potentials (ERPs; P50, P300, N100 and mismatch negativity
[MMN]);
Neuropsychological tests
* Animal fluency test;
* Clinical Dementia Rating scale (CDR);
* Alzheimer*s Disease Assessment Scale * Cognition (ADAS-Cog);
* Amsterdam Instrumental Activities of Daily Living scale (Amsterdam iADL);
* Pittsburgh Sleep Quality Index (PSQI).

Biochemical outcome variables

#### CSF biomarkers

- \* A\* concentration (1-40, 1-42)
- \* Total tau concentration (Tau-t)
- \* Phosphorylated tau concentration (Tau-p)
- \* Exploratory markers (e.g. Neurogranin, VILIP-1)

Exploratory plasma biomarkers

- \* A\* concentration (1-40, 1-42)
- \* Tau-t and Tau-p concentrations
- \* Acute phase & inflammatory proteins

Genetics

\* APOE genotype

#### **Secondary outcome**

Not applicable

# **Study description**

#### **Background summary**

The NeuroCart, a computerized battery of cognitive tests, is used in CHDR's clinical trials to study pharmacodynamic drug effects. There is a growing demand for studies in elderly subjects and further investigation of the use of the NeuroCart in elderly is needed.

#### **Study objective**

Main objectives:

To determine differences in NeuroCart profiles in different sub-groups based on cognitive testing and CSF biomarker profiling (i.e. cognitively normal, pre-symptomatic AD, prodromal AD, MCI, mild AD).

To characterize a cohort of elderly subjects in order to yield norm scores for specific NeuroCart tests in the different sub-groups that will be defined based on cognitive testing and CSF profiling.

#### Exploratory objective:

To determine the correlation between AD-specific biomarkers in plasma and in CSF (A\* 1-40 and 1-42, tau proteins and exosomes) in this cohort of elderly subjects.

#### Study design

This study is a cross-sectional, single occasion, observational study.

#### Study burden and risks

#### Burden:

The burden for the participants includes the time investment for the briefing, screening, the occasion.

#### Risk:

No risks are considered. Only the taking of blood samples can be painful and lead to bruising. The collection of CSF fluid via a lumbar puncture can be painful and lead to post-punction headache.

## **Contacts**

#### **Public**

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#### **Scientific**

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# **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

#### Inclusion criteria

- 1. Males and females, aged 60 and older (inclusive);
- 2. Willing and able to perform the cognitive tests, as evidenced by performance on the training session of the cognitive tests.
- 3. Willing and able to give written informed consent and to comply with the study procedures.

#### **Exclusion criteria**

- 1. Legal incapacity or inability to understand or comply with the requirements of the study;
- 2. Evidence of severe cognitive deterioration, as indicated by a diagnosis of severe cognitive disorder (including but not limited to Alzheimer\*s disease, Lewy Body Dementia, Frontotemporal Dementia);
- 3. History or symptoms of significant psychiatric disease (including but not limited to clinical depression, schizophrenia);
- 4. A Mini Mental State Examination (MMSE) score of < 18;
- 5. A Geriatric Depression Scale (GDS) score of \*6;
- 6. Presence of drug abuse, or positive urine drug screen (UDS) at screening or occasion;
- 7. Presence of severe alcohol abuse (daily alcohol consumption exceeding 2 standard drinks per day on average for females or exceeding 3 standard drinks per day on average for males (1 standard drink = 10 grams of alcohol)), or a positive breath alcohol test at screening or occasion;
- 8. Any other reason that it is not safe or ethical to allow a subject to participate in the study in the opinion of the investigator.

# Study design

## **Design**

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Will not start

Enrollment: 1000

Type: Anticipated

# **Ethics review**

Not approved

Date: 08-03-2016

Application type: First submission

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

(Assen)

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register ID

CCMO NL55747.056.16