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

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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, Fronto-temporal 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