An fMRI and EEG study in patients with mild to moderate Alzheimer’s disease and healthy elderly controls

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21111

Source
NTR

Health condition

Alzheimer's disease, healthy volunteers, biomarker

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

fMRI memory task - BOLD activity

fMRI perception task - BOLD activity

EEG based technique to measure longterm potentiation- amplitudes and latencies

auditory steady state response - gamma oscillations

Secondary outcome

fMRI resting state - default mode network

Evoked related potentials - amplitude and latencies

Study description

Background summary

For the early phase development of M1 and M4 receptor agonists (future treatment for Alzheimer’s disease), suitable biomarkers are required to measure the drug effects. In this study the feasibility of performing several fMRI and EEG based measurements in patients with AD will be assessed, and the difference in these biomarkers between patients with AD and healthy elderly will be evaluated.

Study objective

Patients with Alzheimer's disease have a significantly reduced function of the visual path compared to healthy people.

Study design

no fixed timepoints

Intervention

fMRI memory task

fMRI perception task

fMRI resting state

Evoked related potentials

EEG based technique to measure longterm potentiation

auditory steady state response

Contacts

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Eligibility criteria

Inclusion criteria

All subjects:

1. Aged 50-75 years;

2. Ability to communicate well with the investigator in the Dutch language;

3. Willing to give written informed consent and to comply with the study restrictions;
Additional inclusion criteria for the AD subjects are:

4. Diagnosed with probable AD according to the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria confirmed by the treating physician;

5. MMSE score 18-26 (inclusive);

6. CDR global rating score of 0.5 or 1.0 at screening;

Additional inclusion criteria for the healthy controls are:

7. MMSE score ≥ 27.

Exclusion criteria

All subjects:

1. Any contra-indications for MRI (prostheses, implants, claustrophobia, pacemakers, etc.);

2. Presence or history of alcohol abuse, or 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 upon admission to the Clinical Research Unit (CRU);

3. Use of tobacco and/or nicotine-containing products within 30 days of day 1;

4. Positive urine drug screen at screening or day 1;

5. Unable to refrain from use of (methyl) xanthine (e.g. coffee, tea, cola, chocolate) from 24 hours prior to day 1 until discharge from the CRU;

6. Use of concomitant medication which influences the central nervous system;

7. Concussion or other acute head trauma in the past six months.

8. A Geriatric Depression Scale – 15 (GDS) score ≥6;

Exclusion criteria for AD subjects are:

9. Clinically relevant history of abnormal physical or mental health, other than AD, interfering with the study as determined by medical history taking obtained during the screening visit and/or at the start of day 1 as judged by the investigator (including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder).

10. Use of cholinesterase inhibitors, Memantine or herbal treatments such as Ginkgo Biloba.
Exclusion criteria for healthy subjects:

11. Clinically relevant history of abnormal physical or mental health interfering with the study as determined by medical history taking and physical examinations obtained during the screening visit and/or at the start of day 1 as judged by the investigator (including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-07-2018
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-06-2018
Application type:	First submission

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
NTR-new	NL7145
NTR-old	NTR7343
Other	NL65882.056.18 : chdr1814

Study results