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

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON21111

**Bron**
NTR

**Aandoening**

Alzheimer's disease, healthy volunteers, biomarker

### Ondersteuning

**Primaire sponsor:** Centre for Human Drug Research
**Overige ondersteuning:** fund=initiator=sponsor

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

fMRI memory task - BOLD activity<br>
fMRI perception task - BOLD activity<br>
EEG based technique to measure longterm potentiation- amplitudes and latencies<br>

auditory steady state response - gamma oscillations<br>

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

no fixed timepoints

### Onderzoeksproduct en/of interventie

fMRI memory task

fMRI perception task

fMRI resting state

Evoked related potentials

EEG based technique to measure longterm potentiation

auditory steady state response

# Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |

| | |
|---|---|
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 15-07-2018 |
| Aantal proefpersonen: | 24 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

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|---|---|
| Datum: | 26-06-2018 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7145 |
| NTR-old | NTR7343 |
| Ander register | NL65882.056.18 : chdr1814 |

# Resultaten