Hippocampal subregions volumes at 7 Tesla MRI in patients with early Alzheimer's disease and older persons with normal cognition

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Primary Objective: To examine which subregions of the hippocampal formation on 7 Tesla MRI are most affected in patients with early Alzheimer*s disease compared with older persons with normal cognition. Secondary Objectives:a) To explore risk...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON37919

Source
ToetsingOnline

Brief title
Hippocampal subregions at 7 Tesla MRI in AD

Condition

- Structural brain disorders

Synonym
Alzheimer's Disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: VIDI M Geerlings;VIDI G Biessels

Intervention

Keyword: Alzheimer's disease, brain imaging, cognition, hippocampal formation

Outcome measures

Primary outcome

The primary outcome measure is hippocampal subregion volumes at 7 Tesla MRI.

Secondary outcome

The secondary outcome measure is cognitive functioning.

Study description

Background summary

Hippocampal atrophy is one of the distinctive features of Alzheimer*s disease (AD), distinguishing persons with normal cognition from patients with mild cognitive impairment (MCI) or dementia. The hippocampal formation consists of several subregions that are anatomically distinct and may be differently affected by AD, normal ageing and risk factors. With 7 Tesla MRI, these subregions can now be visualized for the first time in vivo. This can help to understand the etiology of normal and pathological brain aging and to distinguish between normal age-related changes and very early AD.

Study objective

Primary Objective: To examine which subregions of the hippocampal formation on 7 Tesla MRI are most affected in patients with early Alzheimer*s disease compared with older persons with normal cognition.

Secondary Objectives:
a) To explore risk factors for volume reduction in hippocampal subregions on 7 Tesla MRI in patients with early Alzheimer*s disease and older persons with normal cognition.

b) To explore the relation between variation in hippocampal subregion volumes and specific aspects of cognitive functioning, in particular memory, within the group of patients with early Alzheimer*s disease and within the group of older

persons with normal cognition.

Study design

cross-sectional study

Study burden and risks

All research procedures are executed during a single visit to the UMCU. Health risks associated with the procedures and techniques used are minimal. The main burden is the visit to the UMCU to perform the measurements. Furthermore, a venipunction and MRI scan can be uncomfortable for some people.
At the moment no treatment is known that is able to prevent or cure AD, or to substantially delay progression of the disease. This study aims to gain insight in etiology and neurobiological substrate of AD en can contribute to development of new imaging biomarkers of AD that can be used in future observational and intervention studies.

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

Patients:
- Age >= 60 years
- Diagnosis problable or possible AD, or a precursor (amnestic MCI)
- Clinical Dementia Rating Scale (CDR) 0.5 or 1
- Mini-Mental State Examination (MMSE) > 20;Persons with normal cognition:
- Age >= 60 years
- No clinical diagnosis of MCI or dementia, or other neurological conditions that affect cognition
- No previous medical evaluations for cognitive complaints
- Clinical Dementia Rating Scale (CDR) 0

Exclusion criteria

Patients and older persons with normal cognition:
- Contra indications for MR imaging (see appendices A and B of research protocol)
- Not being able to understand Dutch language

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2013
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	11-04-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38101.041.11