In vivo imaging of amyloid-beta deposition in Alzheimer's disease

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1) to assess whether in-vivo abnormalities related to amyloid-β depositions can be detected in the cortical grey matter of AD patients using a 7T MRI system, and 2) to assess whether these abnormalities can be quantified. The future goal is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33273

Source
ToetsingOnline

Brief title
Amyloid imaging

Condition

- Other condition

Synonym
cognitive dysfunction, dementia

Health condition

hersenaandoening

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: CTMM

Intervention

Keyword: Alzheimer's disease, amyloid-beta, MRI

Outcome measures

Primary outcome

The main study parameter will be a qualitative measure of the presence of

distinct hypointense cortical foci and an inhomogeneous aspect of the cortex.

Secondary outcome

The secondary study parameter will be a quantitative measure of susceptibility

related changes in the cortex.

Study description

Background summary

One of the histological hallmarks of Alzheimer*s disease (AD) is the presence of amyloid plaques. Previous research showed that granular hypointense foci in the cortical grey matter and an inhomogeneous cortex could be visualized in post mortem human brain specimens with AD in clinically acceptable acquisition times. These abnormal features were ascribed to the presence of amyloid depositions, and are probably based on the susceptibility artefacts caused by iron which co-localizes with amyloid depositions.

Study objective

1) to assess whether in-vivo abnormalities related to amyloid-β depositions can be detected in the cortical grey matter of AD patients using a 7T MRI system, and 2) to assess whether these abnormalities can be quantified. The future goal is to be able to use 7T MRI as a diagnostic tool for the in-vivo diagnosis of Alzheimer*s disease.

Study design

Observational cross sectional case-control study.

Study burden and risks

This is a non-therapeutic group relatedness study. In order to achieve the aim of the study AD patients are needed, because of the high likelihood of the presence of amyloid plaques. The study consists of one single MRI scan that has no consequences for the health of the participants. MRI contra-indications will be carefully investigated per subject to minimize the risks. Burden will be kept to a minimal by using a short MRI protocol and selecting only those subjects who felt comfortable during their previous MRI scan.

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

- Diagnosed with probable Alzheimer's disease
- Diagnosed as memory complainer
- Capable of giving informed consent

Exclusion criteria

- Contra-indication to MRI scanning:
• Claustrophobia
• Pacemakers and defibrillators
• Nerve stimulators
• Intracranial clips
• Intraorbital or intraocular metallic fragments
• Cochlear implants
• Ferromagnetic implants
• Hydrocephaluspump
• Intra-utrine device
• An iron wire behind the teeth
• Permanent make-up
• Tattoos above the shoulders
- MMSE < 19 points
- Severe physical restrictions (completely wheelchair dependent)
- Fear or problems during the 3T MRI scan
- Age above 90

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL27259.058.09