

Microvascular lesions in the brain in Alzheimer*s disease: identification of a novel biomarker with 7T MRI

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1) To determine if microinfarcts can be detected in the brain with 7T MRI in AD patients2) To determine the prevalence and number of cerebral microbleeds on 7T MRI in patients with AD and to relate these lesions to cognition and to the vascular risk...

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

Summary

ID

NL-OMON36418

Source

ToetsingOnline

Brief title

Cerebral microvascular lesions in AD

Condition

- Structural brain disorders
- Vascular haemorrhagic disorders

Synonym

Alzheimer Disease, Dementia

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alzheimer's disease, brain imaging, cognition, microvascular lesions

Outcome measures

Primary outcome

The prevalence and total number of microinfarcts at 7T

The prevalence and total number of microbleeds at 7T

For the pearsnoer project participants will already receive a full clinical assessment, neuropsychological tests and a 3T MRI.

Participants in the present study will also undergo some additional neuropsychological tests and a 7T MRI.

Secondary outcome

- Conventional brain MRI markers of AD (atrophy) and vascular lesions (large infarcts, white matter hyperintensities) at 3T MRI
- Cognitive profile
- Vascular risk factor profile

Study description

Background summary

Microvascular lesions in the brain are a new lead in the etiology of Alzheimer's disease (AD). High field strength MRI at 7T should greatly facilitate the detection of these lesions. We expect that 7T MRI allows us, for the first time, to detect microinfarcts in living patients. Moreover, we expect that 7T MRI offers new insights in the relation between microbleeds, cognition and other relevant clinical variables.

Study objective

- 1) To determine if microinfarcts can be detected in the brain with 7T MRI in AD patients
- 2) To determine the prevalence and number of cerebral microbleeds on 7T MRI in patients with AD and to relate these lesions to cognition and to the vascular risk factor profile in these patients.

Study design

This is an observational cross-sectional pilot study at the UMC Utrecht.

Study burden and risks

The physical or psychological risk of the study protocol is minimal. There are no health risks associated with the procedures and techniques used. The additional time required for this protocol is limited to 90 minutes. Lying still in the noisy, small tube of the MRI scanner can be uncomfortable. Therefore, special attention will be given to inform subjects about the scanning procedure. A 30 minute scan protocol is part of regular clinical practice for AD. Our experience is that patients are able to undergo this procedure without problems. The main difference with daily clinical practice is the fact that patients receive two scans instead of one.

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

Participant of *parelsnoer neurodegeneratieve ziekten* project and diagnosed with (possible)

Alzheimer's disease.;For pparelsnoer:

referred to memory clinic

subjective and/or objective cognitive impairment

CDR 0, 0.5 or 1

MMSE 20 or higher

Exclusion criteria

Normal pressure Hydrocephalus, M. Huntington

Recent CVA (<2 years), or CVA with subsequent (within 3 months) cognitive deterioration

(History of) Schizophrenia, other psychotic disorders

Major depression

Alcohol abuse

Brain tumour, epilepsy, encephalitis

Absence of reliable informant

Expectation that patient can not be followed for at least 1 year.

Contra-indication for 7 Tesla MR imaging

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	22-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	29-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	16-03-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	12-07-2011
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	NL29817.041.09