Identification of biomarkers sensitive to disease progression in patients with Mild Cognitive Impairment: a two-part clinical study.
Part A: Multisite MRI Acquisition - Protocol Harmonization
Part B: Identification of biomarkers sensitive to disease progression in patients with Mild Cognitive Impairment: a clinical study

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* To implement a standardised MRI acquisition protocol in multiple centres across Europe (Part A).* To identify and evaluate new biomarkers of disease progression in patients with amnestic MCI by collecting biochemical, neuroimaging,...

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

Summary

ID

NL-OMON38870

Source
ToetsingOnline

Brief title
PharmaCog

Condition

- Structural brain disorders

Synonym
Mild Cognitive Impairment, objective memory impairment without dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Alzheimer's disease, Biomarkers, Disease progression, Mild Cognitive Impairment

Outcome measures

Primary outcome

Changes of the hippocampal volume between the two groups (CSFP and CSFN) and

within the same group over time.

Secondary outcome

* Neuropsychological progression and conversion to dementia.

* Change in structural, functional, neurophysiological, biochemical biomarkers

and their combination, i.e. MATRIX and their correlation with change in

cognition and hippocampal volume.

Study description

Background summary

In order to facilitate drug development in Alzheimer*s disease (AD) there is an urgent need for markers for early diagnosis and disease progression. Subjects with Mild Cognitive Impariment (MCI) are at an increased risk to develop

AD-type dementia and may be candiates for early intervention studies.

Study objective

* To implement a standardised MRI acquisition protocol in multiple centres across Europe (Part A).
* To identify and evaluate new biomarkers of disease progression in patients with amnestic MCI by collecting biochemical, neuroimaging, neuropsychological and neurophysiological data in MCI patient with high and low CSF levels of Abeta 42 and follow those patients over time to evaluate the sensitivity for disease progression of each biomarker individually or in combination, and see how those biomarkers correlate with patients cognitive decline (Part B).

Study design

Multi-center longitudinal cohort study

Study burden and risks

Burden:
Participants are patients with a diagnosis of Mild Cognitive Impairment (MCI) without dementia. During two years they will undergo four times a neuropsychological assessment, four MRI's will be made and two lumbar punctures will be done. Similar research showed that burden is acceptable voor these patients.
Risk:
Taking spinal fluid constitutes no significant risk. During this procedure, subjects may have temporary pain and discomfort in your back. The puncture causes headaches in fewer than 4% of cases, and such headaches will subside after a few days at the most. Removal of blood by a needle and syringe can occasionally be painful, but this is temporary. Some people may experience fainting or dizziness, and there is a slight possibility to have infection at the site of the needle stick. MRI can be regarded as a safe neuroimaging technique. An MRI may cause possible anxiety due to the loud banging made by the machine and the confined space of the testing area. Subjects will be informed that they are free to withdraw at any time during the study should they experience excessive anxiety or malaise.

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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 with a diagnosis of Mild Cognitive Impairment, aged 55-90 years and memory complaints verified by a physician and on cognitive testing.

Exclusion criteria

Ischaemic lesions
Head injury with loss of consciousness > 24 hours
Current substance abuse or therapy with steroids or chemotherapy
Systemic disease with frequent involvement of the CNS
CNS disease diagnosed or in treatment
Inadequate for neuropsychological testing
Enrolment in other trials/studies not compatible with this study
Use of specific medication
(History of) neurological/psychiatric illnesses

Ferromagnetic implants and devices not eligible for MRI scanning

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):	26-06-2013
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43073.029.13