National Initiative Brain and Cognition. Functional markers for cognitive deficits - dementia

Published: 24-05-2011
Last updated: 27-04-2024

The purpose of this study is the expansion of the conventional MRI sequences for the diagnosis for patients with probable dementia. The focus is on structural imaging, anatomical and functional connectivity. Patterns of change in brain connectivity…

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

Summary

ID

NL-OMON35818

Source
ToetsingOnline

Brief title
Brain and Cognition

Condition

- Structural brain disorders

Synonym
Alzheimer's disease, dementia, neurodegenerative disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alzheimer's disease, frontotemporal lobar degeneration, Magnetic resonance imaging

Outcome measures

Primary outcome

1.) MRI data: gray matter atrophy, fractional anisotropy, functional

connectivity

2.) Changes over time in the MRI data

Secondary outcome

n.a.

Study description

Background summary

There are many different forms of dementia. Two common forms are Alzheimer's disease and frontotemporal lobar degeneration (FTLD). Until now, the diagnoses are based on clinical criteria and neuropsychological testing. However, the frequent overlap of the clinical syndromes associated with AD and FTLD poses serious problems to a reliable diagnosis. Recently, more accurate techniques like MRI have been developed. In the diagnostic work-up of dementia, MRI is only used supplementary but provides valuable information. The conventional MRI sequences and visual rating scales for MRI do not provide enough sensitivity for an early and accurate diagnosis of AD, and even less so for FTLD. Hence, there is a strong need for quantitative image analysis techniques and for additional scan sequences, with which not only specific structures but the whole brain and brain networks can be assessed. With this early, reliable (differential) diagnoses kan be made.

Study objective

The purpose of this study is the expansion of the conventional MRI sequences for the diagnosis for patients with probable dementia. The focus is on structural imaging, anatomical and functional connectivity. Patterns of change in brain connectivity and -structure and the change over time are the focus of attention to possibly develop a diagnostic tool for AD and FTLD.

Specific research goals:
1) How do patterns of atrophy, white matter tracts and functional connectivity change in different brain regions in AD in comparison to FTLD and healthy controls? How is functional connectivity related to the structure of the brain?
2) How do functional connectivity and brain structure change over a period of one and two years in AD in comparison to FTLD and healthy controls and how can this be linked to a specific diagnosis?
3) Do these changes between baseline and follow-up provide advantages as a diagnostic biomarker over a one-time measurement at baseline?
4) Do changes in functional connectivity correlate with changes in anatomical connectivity?
5) Is there a relationship between the severity/stage of dementia and regional atrophy, anatomical connectivity between brain regions and/or functional connectivity?

Study design

This project is a prospective longitudinal structural and functional MRI study conducted in two medical centres (VU University medical center, Amsterdam and Leiden university medical centre). Data from structural and functional MRI, demographic, clinical and neuropsychological data will be obtained over a period of 2 years. Clinical follow-up is scheduled after 12 and 24 months.
If the baseline scan of patients diagnosed with AD or FTLD does not include all necessary sequences for our study, patients will be asked to return for the missing MRI sequences (20 min) to complete the MRI protocol. At follow-up all patients will undergo the repeated complete MRI scan (50 min) and neuropsychological tests (1 hour). At baseline and at follow up age-matched controls will undergo a complete MRI scan (50 min) a neuropsychological screening (1 hour) and a physical examination by a medical doctor (30 min).
To examine the reproducibility of the MRI data between the two medical centres, 20 subjects will be asked to undergo a MRI scan at both centres.

Study burden and risks

MRI: participants are not exposed to invasive methods or other hazardous circumstances.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
1081 HZ Amsterdam

NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
1081 HZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Competent patients referred to a memory clinic of one of the participating university medical centers, who have objective memory complaints, a CDR score of 0,0.5 or 1 and a MMSE score ><=18. Patients have to be diagnosed with Alzheimer's disease or frontotemporal lobar degeneration according to the clinical criteria of the NINCDS-ADRDA or the consensus criteria for frontal-temporal lobar degeneration respectively.
Healthy controls have to have normal clincial investigations and no significant cognitive deficits.

Exclusion criteria

Patients:
- MMSE score <18
- neurological and/or psychiatric disease
- MRI contra indications
Healthy controls:
- articulate cognitive deficits
- other neurological and/or psychiatric disease
- MRI contra indications

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-08-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2011
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	NL35502.029.11