Brain Network analysis in early onset dementias: Magnetoencephalographic measurements.

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

Summary

ID

NL-OMON41293

Source
ToetsingOnline

Brief title
Brain Network analysis in early onset dementias.

Condition

- Structural brain disorders
- Dementia and amnestic conditions

Synonym
Cognitive Impairment, Dementia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain Network, Dementia, Functional Connectivity, Modularity

Outcome measures

Primary outcome

Primary end points are differences in measures of coupling and organization of MEG functional brain networks between the subject groups. These measures (specified below) are computed after signal pre-processing described by Hillebrand et al. in 2012 with the title: "Frequency-dependent functional connectivity within resting-state networks: an atlas-based MEG beamformer solution".

Functional coupling measure as main study parameter is the Phase Lag Index (PLI). Network measures that will be computed are: clustering coefficient, path length, degree correlation, and modularity (with Synchronization Likelihood as coupling measure (18;19). Correlations of these measures with cognitive performance are generated in the patient groups.

Secondary outcome

Secundary endpoints of the study are:

- relationship of basic quantitative measures (band power, peak frequency) with cognition.

- location of important points in the network (hubs) and the relationship with cognitive performance.

- The Minimal Spanning Tree (MST) configuration, as a different way to construct a brain network (20), and the relationship with cognitive performance

in the patients.

Study description

Background summary

Dementia has a devastating effect on quality of life for both late- and early onet patients. Early-onset dementia, defined as the start of symtpoms before the age of 70, can have several causes, the most prevalent cause is Alzheimer*s disease (AD). In elderly patients, AD consist of progressive memory impairment followed by global cognitive decline. Early-onset AD patients more often show focal impairments like aphasia and apraxia and a more rapid cognitive decline. These symptoms are often referred to as *non-memory* or *atypical* AD presentation.
Other forms of dementia, such as frontotemporal dementia (FTD), semantic dementia (SD), primary progressive aphasia (PPA), corticobasal dementia (CBD), progressive supranuclear palsy (PSP) or dementia with Lewy Bodies (DLB), although rare, are more common in younger patients and may mimic early-onset AD clinically. Most often no structural abnormalities are seen on magnetic resonance imaging (MRI) scanning of the brain, posing diagnostic difficulties.
Brain activity can be measured by magnetoencephalography (MEG). Of this activity, functional networks can be derived by establishing the coupling between brain regions.

Study objective

With this research we intend to fill the gap described in the previous chapter by:
1) Detecting functional network changes in several causes of early-onset dementia and to characterize the specific changes for each dementia cause.
2) Relating specific network changes to specific cognitive deficits.
This will provide insight on the development of functional changes due to the dementias and if distinct patterns are found, this knowledge aids in the diagnostic process.

Study design

After completing a written informed consent, all patients fulfilling the inclusion criteria, as will be described in the next chapter, will undergo an MEG measurement at the MEG centre of the VU medical centre in Amsterdam. This study is designed as an observational cross-sectional study. For control participants which don't have an MRI/NPO formt he past three years, these will be conducted as well.

Study burden and risks

There is no direct therapeutic effect or other benefit in this study; clinical decision making will not be based on the results. The test is non-invasive, short of duration and pain free. Risks associated with participation are negligible, and the burden is minimal. Unexpected findings which could lead to medical treatment will be discussed with participants.

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

- For the patient group: diagnosis of one of the following types of dementia: AD, FTD, SD/PPA, CBD or PSP/DLB.

- For the control group: no past history of cognitive disabilities or other neurological or other disease possibly interfering with the analysis.
- MMSE-score of 18 or higher.
- Age 70 years or younger at the time of participation.
- Written informed consent.

Exclusion criteria

- Previous brain surgery.
- Insufficient mastery of Dutch or English language.
- Conditions that will cause excessive MEG artefact (cardiac pacemaker / cardiac or neural defibrillators, metal fragments in the eyes, metal plates, pins or bolts in head, any magnetic implantation / implantations made from iron (ferrous products)
- For the patient group: lack of MRI examination performed in the last three years or lack of neuropsychological examination performed in the last twelve months.
- For the control group: no conducted MRI in the past three years and unable to undergo MRI examination or neuropsychological testing, cognitive deficits.

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):	01-07-2013
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
Application type:	Amendment
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	NL41647.029.13