Brain patterns in patients with neurodegenerative diseases

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Ethical review Approved WMO

Status Recruitment stopped

Health condition type Movement disorders (incl parkinsonism)

Study type Observational invasive

Summary

ID

NL-OMON34830

Source

ToetsingOnline

Brief title

brain patterns

Condition

- Movement disorders (incl parkinsonism)
- Dementia and amnestic conditions

Synonym

dementia, movement disorders

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: stichting Alzheimer Nederland

Intervention

Keyword: brain patterns, FDG-PET, MRI, neurodegenerative diseases

Outcome measures

Primary outcome

Brain patterns will be extracted from the FDG PET and MRI data images. These PET and MRI output data will be used to define a specific disease related pattern for each neurodegenerative brain disease.

Secondary outcome

nvt

Study description

Background summary

The differential diagnosis of neurodegenerative brain diseases may be difficult on clinical grounds only, especially at an early disease stage. Neurodegenerative brain diseases such as Parkinson*s disease (PD), multiple system atrophy (MSA), progressive supranuclear palsy (PSP), corticobasal degeneration (CBD), dementia with lewy bodies (DLB, Alzheimer*s disease (AD) and frontotemporal dementia (FTD) have overlapping features at presentation, while the typical clinical syndrome may become clear only at later disease stages. For this reason, there is increasing interest to use neuroimaging techniques in the hope to discover biomarkers, that is, abnormal patterns of brain structure, energy consumption or network activity which are characteristic of such diseases. Many in vivo brain imaging techniques are nowadays available for this purpose. [18F]-fluoro- deoxyglucose (FDG) PET imaging has been used to identify characteristic patterns of regional glucose metabolism in patients with neurodegenerative brain diseases. With MR based imaging using Voxel Based Morphometry (VBM) analysis, patterns of cerebral atrophy can be detected in an earlier stage of the disease. Diffusion Tensor MRI (DTI) is able to detect such microscopic abnormalities by measuring the directionality of molecular diffusion in brain tissue. Arterial Spin Labelling (ASL) MR-imaging, at which arterial blood water is labelled as an endogenous diffusible tracer for perfusion, allows for quantitative assessment of tissue perfusion. In resting state fMRI subjects are scanned without external stimulus to derive brain connectivity patterns which are assumed to represent a

default-mode network. It is increasingly recognised that combining information derived from different image modalities is essential for improvements in the sensitivity and specificity of proposed biomarkers for neurodegenerative diseases. The method should allow individual patients to be diagnosed at an early stage of the disease.

Study objective

Databases with multimodal brain imaging data (FDG-PET, VBM, DTI, ASL and resting state fMRI) will be created. From these data image features will be extracted, to be used to create a supervised classification method for associating brain patterns to various stages of neurodegenerative diseases.

Study design

In this observational study, 15 subjects per group of patients with PSP, CBD, DLB, AD and FTD will be included. All subjects will undergo neuro(psycho)logical examination as well as 1 FDG PET scan and 1 MRI scan. Patients with PD and MSA as well as 15 gender- and age matched healthy volunteers are already recruited in a previous study (METc 2008/274)

Study burden and risks

The risks associated with participation are considered negligible and the burden can be considered minimal since there is great experience with these PET and MRI investigations in normal diagnostic work up of patients with neurodegenerative brain diseases and significant side effects are not known. This study can not be conducted without the participation of sufficient subjects in each group. This study can contribute to a better understanding and early diagnosis in patients with neurodegenerative brain diseases.

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

fulfill the typical clinical diagnostic research criteria for PSP,CBD, DLB, AD or FTD and MMSE >=18

Exclusion criteria

claustrofobia or other exclusion criteria for MRI scanning. Other systemic diseases who can cause listed complaints.

Study design

Design

Study type: Observational 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): 01-04-2010

Enrollment: 75

Type: Actual

Ethics review

Approved WMO

Date: 12-03-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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 NL30821.042.09