Diagnostic validity for combined FDG and PIB-PET in Alzheimer*s disease (AD) and differential diagnosis; a regional and multivariate analysis

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The results of the combined [11C] PIB and [18F] FDG PET patterns data and the clinical diagnosis are used in a multimodal, multitracer andmultivariate analysis approach to demonstrate regional and voxelwise correlations.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41948

Source
ToetsingOnline

Brief title
'Dual PET' in dementia

Condition

- Other condition

Synonym
Alzheimers' disease; dementia

Health condition

neurodegeneratieve aandoening/ dementie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: (start) Budget Alzheimer Research Centre

Intervention

Keyword: Amyloid, Biomarkers, Dementia, PET scan

Outcome measures

Primary outcome

The results of the PET imaging data and the clinical diagnosis are used in a multimodal, multitracer and multivariate analysis approach to demonstrate regional and voxelwise correlations between FDG PET and PIB PET. SSM/PCA will be applied using software written in-house, based on method of Eidelberg research group (14) with a univariate and multivariate analyis method. Outcome is measured in so-called z-scores.

Secondary outcome

The correct differentiation of AD between normal healthy controls (CP) and frontotemporal dementia (FTD) and Lewy Body dementia (DLB).

Study description

Background summary

Alzheimer*s Disease (AD) is a progressive dementing and neurodegenerative disorder that is characterized by accumulation of extracellular amyloid plaques

and
intracellular neurofibrillary tangles. Since the development of in vivo biomarkers,
the pathophysiological process is becoming more important in clinical diagnosis, as
recommended in the National Institute on Aging -Alzheimer Association (NIA-AA). PET
biomarkers are Pittsburgh compound-B [11C]PIB, an amyloid marker, showing increased PIB depositions especialy in the
fronto-temporal region and decreased 18F- fluorodeoxyglucose
(FDG) PET metabolism in the temporo-parietal regions as a marker of downstream neuronal
degeneration. To explain this discrepancy in localisation between the pathological pattern of PIB and FDG PET we will use multivariate analysis based on a Principal Component Analysis (PCA) for combined [18F] FDG PET pattern and the binding
of [11C] PIB PET in AD. Also we will investigate correct differentiation of AD between normal
healthy controls (CP), mild cognitive impairement (MCI) and frontotemporal dementia (FTD) and Lewy Body dementia (DLB).

Study objective

The results of the combined [11C] PIB and [18F] FDG PET patterns data and the clinical diagnosis are used in a multimodal, multitracer and
multivariate analysis approach to demonstrate regional and voxelwise correlations.

Study design

All subjects will undergo two PET scans on the same day with a PET protocol with [11C] PIB
and subsequently [18F] FDG PET. Total duration will be 100 minutes. A follow up neuropsychological assessment will be done, to detect progression of dementia. In a
subgroup of patients follow up investigation will be done because of clinical purposes or by
future ability of new and potential more specific diagnostic PET markers.
PET scans will be performed using a Siemens Biograph mCT integrated PET/CT scanner in
3-dimensional acquisition mode. The properties of this scanner have been reported
elsewhere (32). A low dose CT scan will be acquired before the PET scan to correct the PET
data for attenuation. A [11C] PIB PET and [18F] FDG PET will be performed on the same day.

Intervention

All subjects will undergo two PET scans on the same day with a PET protocol with [11C] PIB
and subsequently [18F] FDG PET. Total duration will be 100 minutes.

Study burden and risks

This study entails minimum risk to the participant. The subjects will visit the Nuclear Medicine department for a combined PET scan with a total duration of approximate 100 minutes. The investigation can contribute for the clinical diagnosis of the
subject. Also the study will contribute valuable scientific knowledge to the fields of dementia
and Nucleair Medicine.

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

Age from 50 - 80 yr
Willingness to cooperate and sign written informed consent

Exclusion criteria

- History of major psychiatric illness
- Medications which may affect outcome
- Cerebrovascular disease with cortical infarcts or a Fazekas- score of 2 or higher
- Pregnancy
- Mentally incompetent to understand full consequence of a written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-05-2016
Application type:	Amendment
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	NL50217.042.15