Tau PET imaging in cognitively normal elderly subjects: A twin approach

Published: 19-12-2018
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This study has been transitioned to CTIS with ID 2024-517634-17-01 check the CTIS register for the current data. The main objectives are to 1) investigate the relation between (longitudinal) tau and amyloid accumulation in cognitively normal...

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

Summary

ID

NL-OMON55503

Source
ToetsingOnline

Brief title
Tau Twin

Condition

- Structural brain disorders

Synonym
Alzheimer's disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Dioraphte;Alzheimer's Association and The Foundation of the American Society of Neuroradiology,Eli Lilly

Intervention

Keyword: Alzheimer's disease, PET, Preclinical, Tau

Outcome measures

Primary outcome

Main endpoints are the association of (longitudinal) tau pathology with amyloid pathology (CSF and/or PET) and the correlation in (longitudinal) tau pathology within monozygotic twin pairs.

Secondary outcome

Secondary endpoints are the relation between (longitudinal) tau and neuropsychological performance, magnetic resonance imaging(MRI), CSF measures and AD risk factors.

Study description

Background summary

Alzheimer*s disease (AD) is the most common type of dementia, characterized by progressive neurodegeneration and a gradual onset of cognitive impairment. Abnormal accumulation of beta amyloid (Aβ) is the first event in AD and is present in 20-40% of cognitively normal elderly. The accumulation of Aβ is considered a necessary, but not sufficient, step towards the development of AD dementia. The accumulation of a second protein, tau, is argued to be closer related to cognitive decline.
The recent introduction of [18F]AV-1451 allows visualization and quantification of tau pathology in the living human brain. As such, [18F]AV-1451 potentially represents the first in vivo biomarker to detect the distribution of tau pathology in the brain. Whole brain imaging with PET sheds light on the question whether and how tau binding correlates with cognitive symptoms, amyloid pathology and cerebral atrophy.

Study objective

This study has been transitioned to CTIS with ID 2024-517634-17-01 check the CTIS register for the current data.

The main objectives are to 1) investigate the relation between (longitudinal) tau and amyloid accumulation in cognitively normal individuals, 2) test the contribution of genetic and non-genetic factors on (longitudinal) tau binding in twins, and 3) test the relation of (longitudinal) tau accumulation with other AD-markers collected in the PreclinAD study. The study will be an add-on to the ongoing Amyloid pathology in cognitively normal elderly subjects (PreclinAD) study (METC 2014.210).

Study design

Prospective, observational study.
Intervention: Subjects will undergo a [18F]AV-1451 PET scan at baseline and 4 year follow-up.

Study burden and risks

Risks associated with participation in this study are related to 1) radiation exposure 2) idiosyncratic reaction to the tracer, and 3) discomfort during scanning 4) study in healthy twins, this group is crucial for studying the earliest pathophysiological changes and the contribution of genetic factors in AD development.

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

Inclusion in PreclinAD study (2014.210) and a subject must be older than 60 years, have received an [18F]flutemetamol amyloid PET scan and/or have a known amyloid status obtained from CSF.

Exclusion criteria

1.Has contra indications for MRI scanning and therefore has not received brain MRI;
2.Has evidence of structural abnormalities such as major stroke or mass on MRI that is likely to interfere with interpretation of PET scan;
3.Has a relevant history of severe drug allergy or hypersensitivity. Relevant severe drug allergies should be determined by the Principal Investigator or Co-Principal Investigator, and any questions about a subject*s eligibility can be directed to Avid Radiopharmaceuticals Inc.;
4.Has ever participated in an experimental study with a tau agent, unless it can be documented that the subject received only placebo during the course of the trial;
5.Has been injected with a previously administered radiopharmaceutical within 6 terminal half-lives or when total yearly radiation exposure exceeds 16.1 mSv for female and 22.4 mSv for male participants.
6.Has a history of severe traumatic brain

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]AV1451
Generic name:	[18F]AV1451

Ethics review

Approved WMO Date:	19-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	23-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2024
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
EU-CTR	CTIS2024-517634-17-01
EudraCT	EUCTR2018-004466-34-NL

Register	ID
CCMO	NL68339.029.18