Amyloid PET in patients with carotid occlusive disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON49144

Source
ToetsingOnline

Brief title
AMYCODE

Condition

- Neurological disorders NEC

Synonym
Carotid occlusive disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Cardiovasculair Onderzoek Nederland (CVON);Hartstichting

Intervention

Keyword: Alzheimer's disease, Carotid occlusive disease, Cerebral perfusion

Outcome measures

Primary outcome

Main endpoint is the difference in [18F]Florbetaben binding potential (BPnd) between the affected hemisphere and the contralateral hemisphere. Second endpoint is the difference in perfusion between hemispheres, using the parametric images of relative trace flow (R1).

Secondary outcome

Secundary outcome measures are the relationship between amyloid-β deposition and relative perfusion (R1), the relationship between amyloid-β deposition and relative perfusion to cognitive functioning and the relationship between amyloid-β deposition and relative perfusion to structural neuroimaging parameters (i.e. vascular brain injury and atrophy) in patients with COD.

Study description

Background summary

Carotid occlusive disease (COD) is a risk factor for cognitive decline. Athero- and arteriosclerosis of the cerebral arteries may cause hypoperfusion in the brain. Cerebral hypoperfusion may be one of the factors contributing to the accelerated deposition of amyloid-β in the brain parenchyma or vasculature, which in turn may contribute to the observed cognitive decline. With position emission tomography (PET), it is possible to quantify the amyloid-β plaque distribution pattern in vivo. We hypothesize that in patients with COD, amyloid-β burden is lateralized towards the hemisphere where the occlusion takes place. In the present study, we investigate whether the distribution of amyloid-β deposition is lateralized in patients with unilateral COD, using quantitative measurements of amyloid with PET.

Study objective

We aim to use quantitative [18F]Florbetaben PET to investigate a potential lateralized distribution of cerebral amyloid-β deposition in patients with COD. To validate the assumption that the hypoperfusion is lateralized, we use relative perfusion (R1) derived from pharmokinetic modeling of the dynamic amyloid PET to investigate differences in perfusion between hemispheres. Secondary objectives: We aim to study the association between deposition and relative perfusion (R1) and between both amyloid-β binding and R1 and clinical measures (cognitive functioning and neuroimaging parameters).

Study design

Cross-sectional, observational study, within subjects.

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) placement of intra-venous catheters.

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

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- At least 55 years of age;
- Occlusion of the internal carotid artery (ICA) as visible on MR or CT angiography, or DSA;
- Mini-mental state examination (MMSE) is higher or equal to 18;
- Patients must, in the opinion of the principal investigator/attending neurologist, be able to tolerate the [18F]Florbetaben PET scan procedures and be competent to make a well in-formed decision to participate in this study;

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in this study:
- Contralateral stenosis of >70% of the ICA or middle cerebral artery (MCA);
- History of vascular reconstructive surgery in the brain;
- Has evidence of structural abnormalities such as mass on MRI that is likely to interfere with the clinical presentation and/or interpretation of PET scan;
- Has ever participated in an experimental study with an amyloid targeting agent, unless it can be documented that the subject received only placebo during the course of the trial;
- Has been injected with a previously administered radiopharmaceutical within 6 months terminal half-lives OR when the total yearly radiation exposure exceeds 10 mSv;
- Has other neurological diagnosis, such as Parkinson*s disease, multiple sclerosis or severe traumatic brain injury, or a major psychiatric disorder;

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2020
Application type:	First submission
Review commission:	METC NedMec

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	NL72646.041.20

Study results

Date completed:	27-02-2023
Actual enrolment:	21