AMYPAD Prognostic and Natural History Study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24549

Source
Nationaal Trial Register

Brief title
AMYPAD PNHS

Health condition

Alzheimer's disease, cognitive decline, Alzheimer's dementia, ziekte van Alzheimer's, dementie, cognitief achteruitgang

Sponsors and support

Primary sponsor: Stichting VUmc
Source(s) of monetary or material Support: Innovative Medicines Initiative Joint Undertaking Grant Agreement No. 115952

Intervention

Outcome measures

Primary outcome

„X Primary Variables

„X Composite Centiloid, SUVR and/or BPND values measured from [18F]flutemetamol or [18F]florbetaben PET images

„X Change from baseline in a composite score comprising measures of cognitive status and daily functioning, modifiable risk factors, and MRI measures of brain atrophy

Secondary outcome

„X Secondary Variables

„X Change from baseline in measures of cognitive status (e.g. RBANS Total Scale Index Score)

„X Change from baseline in MRI measures of brain atrophy

„X Change from baseline in measures of daily functioning

„X Change from baseline in measures of modifiable risk factors

„X Regional SUVR and/or BPND values at baseline

„X Change from baseline in Centiloid, SUVR and BPND values (global and/or regional)

„X Baseline R1 values from dynamic scans

„X Change from baseline in R1 values from dynamic scans

„X Threshold values of Centiloid, SUVR and/or BPND for negative/positive amyloid status that produce the greatest agreement with visual interpretation by a trained nuclear physician or radiologist

„X Threshold values of Centiloid, SUVR and/or BPND for negative/positive/grey-zone amyloid status that produce the highest accuracy with respect to predicting cognitive decline (and/or brain atrophy as measured by MRI)

Study description

Background summary

The Amyloid Imaging to Prevent Alzheimer¡¦s Disease (AMYPAD) Prognostic and Natural History Study (PNHS) is planned as an open label, prospective, multicentre, cohort study linked to the European Prevention of Alzheimer¡¦s Dementia (EPAD) Longitudinal Cohort Study (LCS) (ClinicalTrials.gov Identifier: NCT02804789). For the purpose of phenotyping and disease modelling, the EPAD LCS employs the concept of an Alzheimer¡¦s Disease (AD) risk

probability spectrum that comprises four main dimensions ¡V research participant clinical outcomes (e.g. cognition), disease biomarkers, and traditional risk factors (genetic and environmental) and change in these. With the incorporation of longitudinal change scores as relevant, these dimensions are used to estimate an individual¡¦s overall predicted probability of AD-related decline in terms of a variety of outcomes.

As one application of this strategy, AMYPAD PNHS is a natural history study that will evaluate how amyloid imaging might help improve the understanding of the natural course of AD. The study will assess amyloid positron emission tomography (PET) imaging as an additional and potentially relevant AD biomarker to complement the phenotyping and disease modelling efforts within EPAD LCS. As measured from [18F]flutemetamol and [18F]florbetaben PET images, brain amyloid load will be quantified at baseline and mean temporal change in amyloid load will be estimated when available. The ability to accurately estimate in vivo amyloid load could lead to a better understanding of disease evolution, earlier detection of the disease, and enable researchers to objectively monitor change in amyloid load to measure the impact of novel therapies.

Study objective

That quantitative amyloid imaging analysis has an additional value for modelling and assessing Alzheimer¡¦s Disease (AD) dementia risk in individuals without dementia, compared to a range of existing cognitive, imaging, laboratory and genetic biomarkers.

Study design

T0 - Baseline (amyloid PET imaging session)

T1 - Follow-up between 12-24 months after baseline (amyloid PET imaging session; only applicable for 50% of participants)

Intervention

At least one amyloid PET imaging session, with the possibility of a follow-up scan between 12-24 months after baseline for 50% of participants.

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Baseline Eligibility Criteria

1. Participants who are currently active in the EPAD LCS will be eligible if they provide separate written informed consent to participate in the AMYPAD PNHS.

2. Participants with a suitable baseline biomarker, cognitive and risk factor profile, as determined by the Selection and Feasibility Committee, based on an adaptive selection algorithm that aims to provide optimal representation of the probability spectrum for AD risk; OR participants that have been randomly selected to maintain the mandated non-disclosure in EPAD LCS.

3. Participants who are assessed by the recruiting investigator to be physically fit to undergo PET scanning and able to tolerate the PET scanning procedure for at least the duration of a static scan (20 minutes).

Follow-up Eligibility Criteria

1. Participants who underwent dynamic PET scanning at baseline:

a. Participants who are willing and available to undergo a follow-up scan. All participants with a dynamic scan at baseline will be invited for follow-up scans.

2. Participants who underwent static PET scanning at baseline:

a. Participants who are willing and available to undergo a follow-up scan, and

b. Are selected based on the Selection and Feasibility Committee¡¦s algorithm for follow-up, which in addition to the previous algorithm also considers baseline composite SUVR values.

Exclusion criteria

Exclusion Criteria:

1. Participants who are not currently active in the EPAD LCS.

2. Participants in whom PET scanning or magnetic resonance imaging (MRI) are contraindicated.

3. Participants who are not able to complete the study procedures as judged by the investigator.

4. Participants who have known hypersensitivities to the active ingredients of [18F]flutemetamol and [18F]florbetaben, or the excipients for both products (listed in section 6.1 of the respective Summary of Product Characteristics [SPC]).

5. Women who are pregnant, planning to become pregnant, or lactating.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2018
Enrollment:	2000
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7247
NTR-old	NTR7454
Other	VUmc METC : 2018.357

Study results