AMYPAD Diagnostic and Patient Management study on the value of amyloid PET imaging

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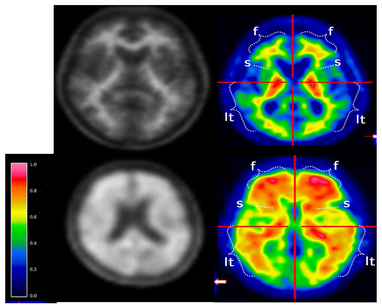
AMYPAD
Amyloid imaging to prevent Alzheimer´s Disease

Background

Amyloid imaging to prevent Alzheimer's disease (AMYPAD) is a collaborative research initiative to improve the understanding, diagnosis and management of Alzheimer's disease (AD) through the utilisation of β-amyloid PET imaging. The 5-year programme is part of the Innovative Medicines Initiative, a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). AMYPAD will have close links with its sister program EPAD (European Prevention of Alzheimer's Disease).

A total of 6000 scans will be performed in AMYPAD split 50:50 between the PET imaging agents NeuraCeq (Piramal Imaging) and Vizamyl (GE Healthcare).

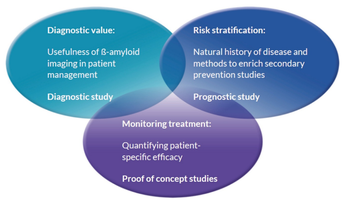


NeuraCeq™ (left column) and Vizamyl™ (right column) axial images.

Upper images depict amyloid negative scans, lower images depict amyloid positive scans.

Goals

AMYPAD has 3 major goals which will be achieved by two major studies and the development of methodology to select the optimal subject groups for therapy studies as well as being able to effectively measure the efficacy of targeted therapeutics.



Diagnostic and Patient Management Study (DPMS) Design

The Diagnostic and Patient Management Study is an open label, randomized multicenter study that will enroll 900 subjects in 8 European memory clinics.

Aim

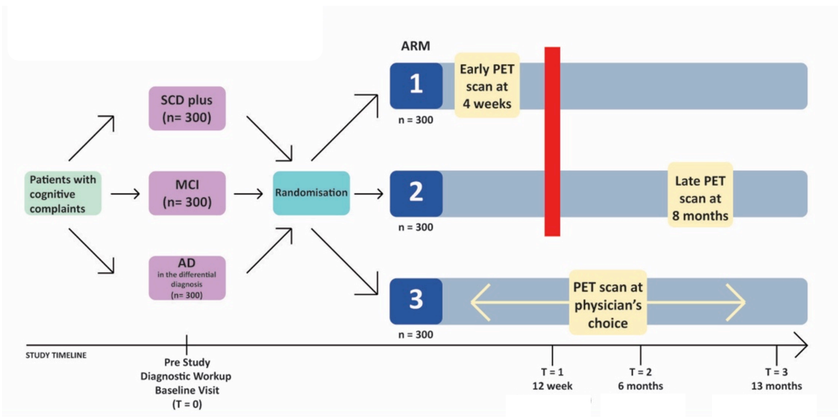
To explore the impact of amyloid PET imaging on diagnostic thinking in subjects with memory complaints being evaluated for Alzheimer's Disease.

Populations

The target population of the study is 300 subjects with subjective cognitive decline (SCD Plus), 300 subjects with Mild Cognitive Impairment (MCI), and 300 subjects with dementia where AD is in the differential diagnosis.

Methods

Patients will be randomized in 3 arms: Early amyloid PET imaging (ARM 1), Late amyloid PET imaging (ARM 2), Free Choice amyloid PET imaging (ARM 3). Only subject randomized to ARM 1 will undergo a second scan at 18 months from the first one.
Amyloid PET imaging will be integrated into the routine diagnostic procedures to evaluate its impact in real life.



Primary Endpoint

To test the hypothesis that at 12 weeks from baseline, a higher proportion of etiological diagnoses with high confidence (≥ 90%) is expected for subjects with amyloid-PET at baseline (ARM 1)

Secondary Endpoints

Diagnosis and Confidence	Patient Management	Health Economic Outcomes	Imaging Assessment
Time to communicate the etiological diagnosis	Number of patient randomized to DMD or other AD clinical trials	Impact of patient reported outcomes	Estimate amyloid deposition over 18 months
Changes in etiological diagnosis over time	Change in Management Plan	Cost of diagnostic work up to high confidence diagnosis	Develop standardized methods of image quantitation
Changes in the likelihood that symptoms are due to AD over time		Differences in use of medical resources in ARM1 vs ARM 2	
Changes over time in utilization of amyloid PET imaging in Free Choice Arm		Number of subject who are discharged by the memory clinic after exclusion of AD	

Discussion

The true potential of amyloid PET to improve outcomes of patients with AD has not been completely realised. The value, timing and appropriateness of amyloid PET imaging in clinical practice need to be established to allow its cost-effective implementation in the diagnostic process of cognitive decline and dementia.
The aim of the Diagnostic and Patient Management Study is to determine the value of amyloid PET imaging in a real-life clinical setting: for whom diagnostic amyloid PET imaging is appropriate, what is its best placement in the diagnostic work up, and how the resulting information is influencing diagnostic thinking, patient management and ultimately decision trees and cost-effectiveness of dementia care.
The study hypothesis is that the early determination of amyloid status of a patient using PET imaging will provide a more accurate diagnosis of the cause for a patient's cognitive decline, and hence will impact patient management, with a reduction in the use of medical resources compared to patients having a delayed scan.

Academic partners

barcelonaβeta BRAIN RESEARCH CENTER · The University of Edinburgh Centre for Dementia Prevention · Karolinska Institutet · Hôpitaux de Toulouse · UCL · VUmc VU University Medical Center Amsterdam · Université de Genève · University of Cologne · Radboudumc · HUG Hôpitaux Universitaires Genève

SMEs

SYNAPSE Research Management Partners · IXICO

Industrial partners

Piramal Imaging · GE Healthcare · Janssen Pharmaceutical Companies of Johnson & Johnson

Patient organisation

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