AMYPAD - A European public-private partnership to investigate the value of β-amyloid brain scans as a diagnostic and therapeutic marker for Alzheimer's disease

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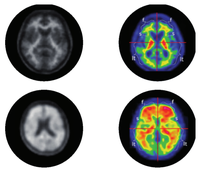
on behalf of the AMYPAD Consortium

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).

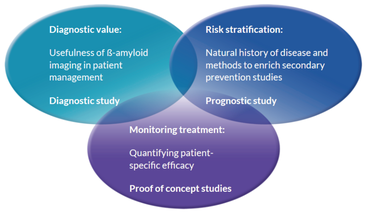


Neuraceq™ (left column) and Vizamyl™ (right column) axial images.

Upper images show amyloid negative cases; lower images show amyloid positive cases

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.



Study Design

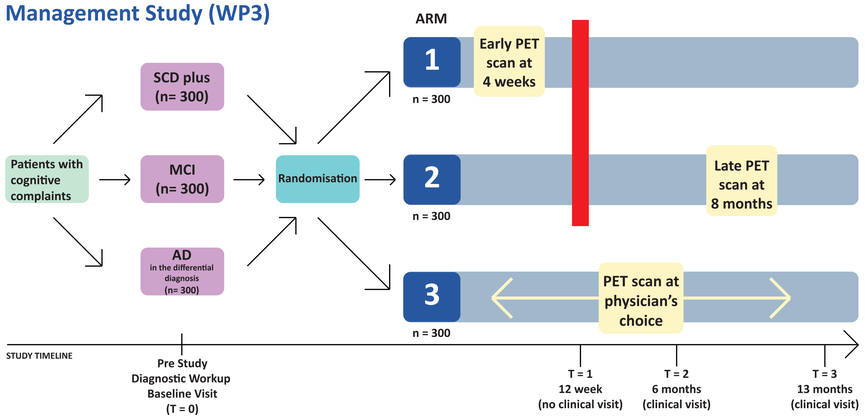
Diagnostic and Patient Management Study (DPMS)
The first clinical study, the Diagnostic and Patient Management Study, will be an open label, randomised study (n=900).

Aim
To explore the impact of amyloid PET on change in diagnosis in patients with memory complaints (MCI or dementia of unclear aetiology) as well as looking at the change in management of those patients being evaluated for subjective cognitive decline.

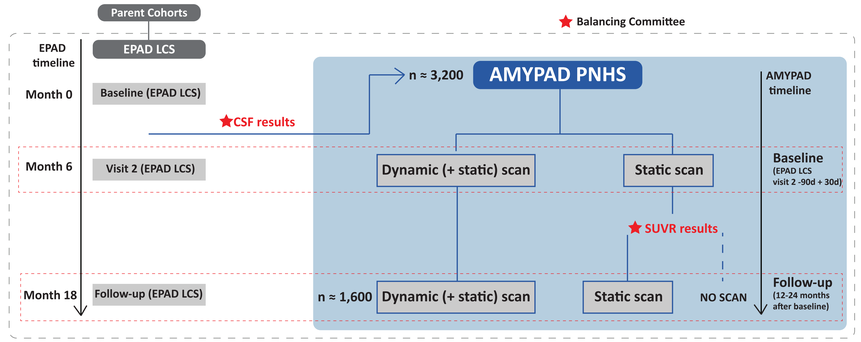
Methods
The study will have 3 arms, the first two having either an early or late PET scan with the third being a 'physician's free choice' arm. Subject work-up during the study will be integrated into routine clinical diagnostic procedures.

Primary endpoint
The difference at 12 weeks after baseline, between the early imaging arm and late imaging arm in the proportion of patients for whom the clinical doctor has made an aetiological diagnosis with greater than 90% confidence (see red band).

AMYPAD Diagnostic and Patient Management Study (WP3)



AMYPAD Prognostic and Natural History Study (WP4)



LCS - Longitudinal Cohort Study; PNHS - Prognostic and Natural History Study

Prognostic and Natural History Study (PNHS)
The second study, the Prognostic and Natural History Study (subpopulation of the EPAD longitudinal cohort study) will be a natural history cohort with over 3000 subjects.

Aim
To collect data which will contribute towards a well-phenotyped probability-spectrum population for improving disease models for AD in individuals without dementia, as well as aiding subject selection for therapeutic intervention studies.

Methods
Generation of baseline amyloid PET data, as well as dynamic baseline data and longitudinal data in subjects with a wide range of pathological amyloid (negative/grey zone/positive).

Primary Endpoint
Predict progression within an AD risk probability spectrum (derived from four different dimensions: cognition, other biomarkers, traditional genetic and environmental risk factors) based on quantitative PET amyloid imaging measures, with or without other biomarkers.

Partners The AMYPAD programme has budget of €27.3M distributed across a total of 15 partners from the private and academic sectors:

Academic
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

SMEs
SYNAPSE Research Management Partners · IXICO

Industry
janssen Pharmaceutical Companies of Johnson & Johnson · Piramal | Life Sciences knowledge action care · GE Healthcare

Patient organization
Alzheimer Europe

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