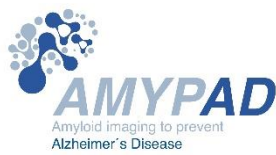
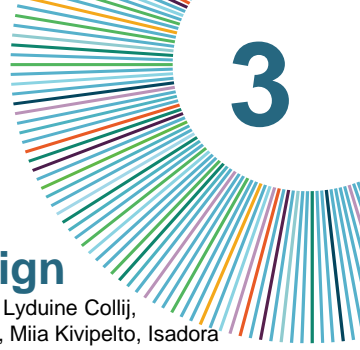


10 YEARS OF
BREAKTHROUGHS
A HEALTHIER
FUTURE



Amyloid imaging to prevent
Alzheimer's Disease



3

AMYPAD Diagnostic and Patient Management Study (AMYPAD-DPMS): rationale and study design

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Facts & Figures

Start date:	01/10/2016
End date:	30/09/2021
Contributions	
IMI funding:	11 999 886 €
EFPIA in kind:	12 233 950 €
Other:	3 095 452 €
Total Cost:	27 329 288 €
Project website:	www.amypad.eu
Social media:	@IMI_AMYPAD

Challenge

Fluorinated amyloid PET (AMY PET) ligands:

- **high analytical validity** to detect brain amyloidosis,
- **approved worldwide** for the diagnostic workup of persons evaluated for Alzheimer's disease (AD);
- **lack of definitive evidence** on their **clinical utility** and **cost-effectiveness**.



AMY PET ligands are not yet reimbursed

Aim of AMYPAD-DPMS → Evaluate the clinical utility and cost-effectiveness of AMY PET.

Approach & Methodology

AMYPAD-DPMS is a phase 4, multicenter, prospective, randomized controlled study, involving **8 European memory clinics**.

Participants

900 patients with suspected AD and presenting:

- Subjective cognitive decline plus (SCD+),
- Mild cognitive impairment (MCI),
- Dementia.

Study design - Patients will be randomized to:

- **ARM 1**, AMY PET performed **early** in the diagnostic workup (within 4 w from baseline);
- **ARM 2**, AMY PET performed **late** in the diagnostic workup (8 m after baseline);
- **ARM 3**, AMY PET performed **whenever** the managing physician chooses to do so.

Endpoints

Primary endpoint → Difference between ARM1 and ARM2 in the proportion of patients receiving an etiological diagnosis with very high diagnostic confidence ($\geq 90\%$) within 3 months.

Secondary endpoints

Diagnosis and diagnostic confidence → Time to communicate to the patient an etiologic diagnosis with very high confidence; Changes in etiological diagnosis and diagnostic confidence over time; How the placement of amyloid PET in the clinical workup changes over time.

Diagnostic/therapeutic management → Number of patients randomized to AD clinical trial after 6 months; Change or early adoption of programs and/or pharmacologic treatments.

Health economics and patient-centered outcomes → Patient-related outcomes (cognition, anxiety, depression, coping skills, and quality of life); Cost of diagnostic workup; Number of patients discharged.

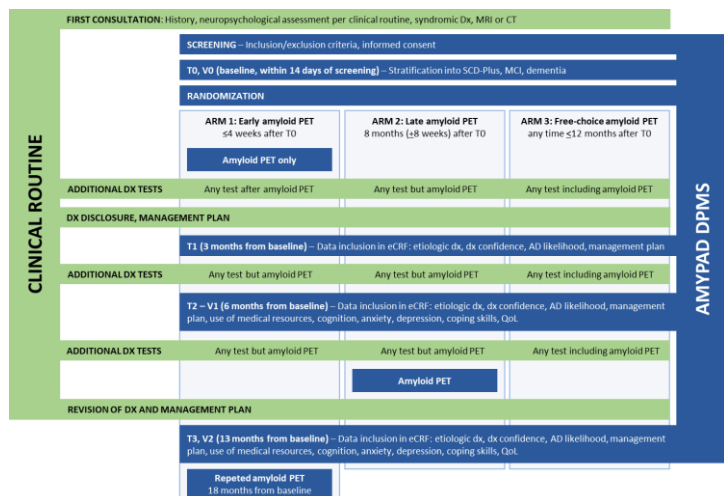
Methods for image quantitation → Test the hypothesis that amyloid load is stable over 18 months. Develop standardized methods of image quantitation across tracers.

Value of IMI collaboration

The IMI collaboration has given us the opportunity to involve European centers with different backgrounds and levels of experience in the project.

Impact & take home message

AMYPAD-DPMS will supply physicians and health care players with real-world data to plan management decisions of patients undergoing diagnostic workup for suspected AD, and health care payers with health-economics data on the clinical utility of AMY PET.



innovative
medicines
initiative



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