New IDEAS Study SCHEMA

Time Point	Participant Events	Data Collection
T1 (Visit 1)	Clinic Visit with dementia specialist: Participant screened for eligibility, consented and referred for Amyloid PET Scan.	Registrar: Submit Case Registration Form and Socio-demographic Form.
T2	NOTE: Dementia Specialist must submit the pre-PET clinical assessment form electronically **within 7 days of registration or the case automatically cancels** and the patient must be entirely re-registered.	Dementia specialist: Submit Pre-PET Form within 7 days of Case Registration.
T3 (Visit 2)	Amyloid PET Scan • Scan cannot begin until AFTER T2 – receipt of Pre-PET form. • Scan must be completed within 60 days of T2.	Imaging Facility Staff: Submit Scan Completion Form within 7 days of the day of scan. Radiologist/Nuc. Med. Phys.: Dictate report and complete PET Report, Assessment Forms. Note: same physician must interpret scans and complete assessment.
T4	Time point at which Dementia specialist discloses results of the Amyloid PET scan. This is a standard of care appointment. Adjustments to patient management may be made if appropriate. THIS IS NOT THE POST-PET VISIT	No data collection is associated with this time point.
T5 (Visit 3)	Clinical visit with Dementia specialist: Clinical visit to assess participant's status, assess whether changes to management made at T4 have been implemented (i.e. adherence to and tolerance of treatment), and to gather data for Post-PET form. This visit should take place approximately 90 days after PET scan, but no less than 60 days and no more than 120 days.	Dementia specialist: Submit the Post-PET form Post-PET form requests status update for each item that had been planned as of the Pre-PET and any new items added since the PET scan.

Dementia Specialist

Radiologist / Nuc. Med. Phys.

Data collection by onsite study staff

TIPS FOR WORKING WITH POTENTIAL STUDY PATIENTS

» Best to verify eligibility **BEFORE** presenting the study to a patient.
- If needed, order structural imaging and lab tests while patient is in the clinic and verify eligibility once results are available before discussing study enrollment.

» Allow sufficient **TIME** for patient and any caregiver to read the consent form or other information (e.g., patient brochure) *before* being asked to sign.

» Use **OPEN ENDED QUESTIONS** to assess understanding of the consent – if the potential subject lacks capacity, seek the consent of a legally authorized representative, such as those named in a durable power of attorney.

» Data collected about the patient regarding their race, ethnicity, gender, and socio-demographics must be **SELF-REPORTED** by the participant or caregiver themselves.

» **DISCUSS** the psychological ramifications of knowing one's amyloid status. Anyone who is likely to be negatively affected by knowing their amyloid status should not be enrolled.

» **REVIEW** required follow-up visits. (Disclosure visit shortly after the PET scan and visit 90-days following the PET scan).
- Consider scheduling these visits once date of PET scan is known.

» **DISCUSS** Medicare reimbursement. Patients may be responsible for unmet beneficiary deductibles, coinsurance or copayments associated with dementia expert visits. Coinsurance amounts associated with the amyloid PET scan (e.g. fixed copayments and technical, professional or global charges) not covered by the patient's insurance will be covered by the study Sponsor, the American College of Radiology. Medicare Advantage plans (Part C) may require pre-authorization. Encourage patients to contact their specific plan to learn more.

NEW iDEAS

Imaging Dementia—Evidence For Amyloid Scanning

New IDEAS: Imaging Dementia — Evidence for Amyloid Scanning Study:

A Study to Improve Precision in Amyloid PET Coverage and Patient Care

Directed by	Alzheimer's Association®
Sponsored and Managed by	American College of Radiology
Advised by	Centers for Medicare & Medicaid Services
Clinicaltrials.gov ID	NCT04426539
Study Chair	Gil D. Rabinovici, MD, University of California, San Francisco, Gil.Rabinovici@ucsf.edu

alzheimer's association®

Learn more at: www.IDEAS-Study.org

STUDY OBJECTIVES/SPECIFIC AIMS

The New IDEAS Study is an observational, open-label, longitudinal cohort study designed to address the requirements of the CED provisions of the NCD on beta-amyloid PET. Building on the initial Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study, New IDEAS will evaluate the association between amyloid PET and patient-centered outcomes in an expanded and more **ethnoracially and clinically diverse** group of Medicare participants presenting with cognitive impairment.

Aim 1:

To compare 12-month claims-derived health outcomes in amyloid PET-positive versus amyloid PET-negative individuals presenting with MCI and dementia in the entire study cohort of diverse Medicare beneficiaries.

Aim 2:

To describe the association of amyloid PET findings with changes in patient management and 12–month claims-derived health outcomes among Blacks/African Americans, Latinx/Hispanics and Whites/Caucasians presenting with MCI and dementia.

Aim 3:

To describe the association of amyloid PET findings with changes in management and 12-month claims-derived health outcomes in individuals presenting with typical (progressive amnestic) versus atypical clinical presentations of MCI and AD dementia.

Additional Objectives:

A. Biorepository – To collect and bank plasma and DNA from a practice based sample of cognitively impaired patients.

B. Image Repository – To collect and archive amyloid PET scans for use in future research

INCLUSION CRITERIA

Note: All inclusion required tests and procedures are considered standard practice.

- Medicare beneficiary.
- Meets clinical criteria for Mild Cognitive Impairment (MCI) or Dementia as defined by the 2018 National Institute on Aging – Alzheimer's Association Research Framework.
- Head MRI and/or CT within 24 months prior to enrollment.
- Clinical laboratory assessment (CBC, comprehensive metabolic panel, TSH, vitamin B12) within 12 months prior to enrollment.
- Able to tolerate amyloid PET required by protocol, to be performed at a participating PET facility.
- Neuropsychiatric syndrome can be classified into "clinically typical" or "clinically atypical" categories.
  - Clinically typical – memory-predominant presentation of MCI and dementia in whom the clinical course and progression are highly suggestive of AD as the underlying cause.
    - Insidious onset of symptoms over months to years, not sudden over hours or days.
    - History of worsening condition by report or observation
    - Initial and most prominent cognitive deficits are impairment in episodic memory. A diagnosis of dementia, impairment in another cognitive domain is required.
  - Clinically atypical - underlying AD is considered a possible cause of MCI and dementia, but are not "clinically typical" because they have one or more of the following features:
    - Primary symptoms not related to memory.
    - Presence of significant co-morbidities that can contribute to cognitive decline.
    - Course of clinical progression is atypical.
    - Clinical Course has mixed features of AD and non-AD dementing illnesses.

EXCLUSION CRITERIA

- Normal cognition or subjective complaints that are not verified by cognitive testing.
- Knowledge of amyloid status, in the opinion of the referring dementia expert, may cause significant psychological harm or otherwise negatively impact the patient or family.
- Amyloid or tau status already known to patient or referring clinician based on prior amyloid imaging or cerebrospinal fluid analysis.
- Previous amyloid PET scan obtained.
- Current or previous treatment with anti-amyloid agent.
- Current or previous enrollment in an anti-amyloid therapeutic trial.
- Scan is being ordered solely based on a family history of dementia, presence of apolipoprotein E (APOE) 4, or in lieu of genotyping for suspected autosomal mutation carriers.
- Scan being ordered for nonmedical purposes (e.g., legal, insurance coverage, or employment screening).
- Cancer requiring active therapy (excluding non-melanoma skin cancer).
- Hip/pelvic fracture within the 12 months prior to enrollment.
- Body weight exceeds PET scanner weight limit.
- Currently pregnant or planning to become pregnant within 90 days of registration.
- Life expectancy less than 24 months based on medical co-morbidities.
- Residence in a skilled nursing facility.

For information about Medicare reimbursement for eligible study participants visit: www.Ideas-Study.org