IDEAS Study SCHEMA

Time Point	Participant Events	Data Collection
T1	Office Visit with dementia specialist: Participant screened for eligibility, consented and referred for Amyloid PET Scan	Registrar: Submit Case Registration 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	Amyloid PET Scan • Scan cannot begin until AFTER T2 – receipt of Pre-PET form • Scan must be completed within 30 days of T2	Imaging Facility Staff: Submit Scan Completion form by midnight of the day of scan Radiologist/Nuc. Med. Phys.: Dictate report and complete PET Assessment Form. Note: same physician must interpret scans and complete assessment.
T4	Office visit 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	Office visit with Dementia specialist: Office visit to assess participant's status, 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 75 days and no more than 105 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.
- Check if structural imaging (MRI and/or CT scans) and lab tests have been completed within last 24 or 12 months, respectively. If needed, order scans/labs 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.

» **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. Be prepared to provide an estimate of out-of-pocket costs. Traditional Medicare plans (Part B) provide 80% of payment; the other 20% may be provided by supplemental insurance plans or self-pay. Medicare Advantage plans (Part C) may have a co-pay or require pre-authorization. Encourage patients to contact their specific plan to learn more. Note: Costs may depend on the type of PET facility (Hospital-based vs. Independent).

MA1701236-0

IDEAS

Imaging Dementia—Evidence For Amyloid Scanning

Imaging Dementia — Evidence for Amyloid Scanning (IDEAS) Study: A Coverage with Evidence Development Longitudinal Cohort Study

Sponsored by	Alzheimer's Association®
Managed by	American College of Radiology, American College of Radiology Imaging Network®
Advisor	Centers for Medicare & Medicaid Services (CMS)
Clinicaltrials.gov ID	NCT02420756
Study Chair	Gil D. Rabinovici, MD, University of California, San Francisco, Gil.Rabinovici@ucsf.edu

alzheimer's association®

Learn more at: IDEAS-Study.org

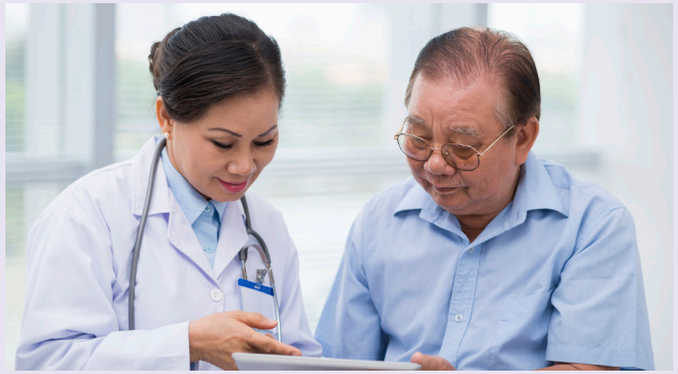
STUDY OBJECTIVES/SPECIFIC AIMS

The Imaging Dementia — Evidence for Amyloid Scanning (IDEAS) Study will establish an open-label, longitudinal cohort study to assess the impact of amyloid PET on patient outcomes under Coverage with Evidence (CED) in patients meeting appropriate use criteria (AUC) for amyloid PET (Johnson et al. 2013).

Our hypothesis is that amyloid PET will decrease uncertainty and increase confidence in the underlying cause of cognitive impairment, that this will translate into earlier counseling and interventions in these domains, and that these interventions will lead to improved outcomes.

Aim 1:
To assess the impact of amyloid PET on the management of patients meeting Appropriate Use Criteria (AUC).

Aim 2:
To assess the impact of amyloid PET on hospital admissions and emergency room visits in patients enrolled in the study cohort (*amyloid PET-known*) compared to matched patients not in the cohort (*amyloid PET-naïve*) over 12 months.



INCLUSION CRITERIA

- 65 years and older.
- Medicare beneficiary.
- Diagnosis of MCI or dementia, according to DSM-IV and/or National Institute on Aging-Alzheimer's Association criteria, verified by a dementia specialist within 24 months (*American Psychiatric Association. 2000; McKhann et al. 2011; Albert et al. 2011*).
- Meets Appropriate Use Criteria (AUC):
  - Cognitive complaint verified by objectively confirmed cognitive impairment.
  - The etiologic cause of cognitive impairment is uncertain after a comprehensive evaluation by a dementia specialist, including general medical and neurological examination, mental status testing including: standard measures of cognitive impairment, laboratory testing, and structural neuroimaging (Head MRI and/or CT).
  - Alzheimer's disease is a diagnostic consideration.
  - Knowledge of amyloid PET status is expected to alter diagnosis and management.
- Head MRI and/or CT within 24 months prior to enrollment.
- Clinical laboratory assessment (complete blood count [CBC], standard blood chemistry profile, thyroid stimulating hormone [TSH], vitamin B12) within the 12 months prior to enrollment.
- Able to tolerate amyloid PET required by protocol, to be performed at a participating PET facility.
- English or Spanish speaking (for the purposes of informed consent).
- Willing and able to provide consent. Consent may be by proxy.

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

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 status already known to patient or referring clinician based on prior amyloid imaging or cerebrospinal fluid analysis.
- 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.
- 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: Ideas-Study.org/medicare-reimbursement/