ForPatients
by Roche

Alzheimer's Disease (AD)

A study comparing different tools for looking at the brain in people with Alzheimer’s disease: tau radiotracers for brain imaging with Positron Emission Tomography (PET)

Evaluation Comparing Two Tau PET Radiotracers, [18F]PI-2620 and [18F]GTP1, in Brains of Participants With Prodromal or Mild Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04566003 GN42801

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Phase 1 Evaluation Comparing Tau PET Radiotracers, [18F]GTP1 and [18F]PI-2620 or [18F]MK-6240 in Subjects With Normal Cognition or Prodromal to Moderate Alzheimer's Disease

Trial Summary:

This study aimed to better understand Alzheimer's disease and improve ways to find tau protein in the brain. People over 65 with normal brain function and those over 50 with Alzheimer's could join. Participants took memory and thinking tests, had health checks, including brain MRIs, and most importantly, had PET scans with three different radiotracers. These scans helped compare the radiotracers' effectiveness in detecting tau and beta-amyloid deposits. The radiotracers were safe to use. The main benefit was the valuable information gained, helping researchers advance in understanding and detecting Alzheimer's disease.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

NCT04566003 GN42801
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 90 Years	No

Inclusion Criteria:

- Cognitively normal subjects aged 65 to 90 years and prodromal to mild AD subjects aged 50 to 90 years, inclusive at the time of screening.
- Prodromal to moderate AD subjects: Meet the National Institute on Aging - Alzheimer's Association (NIA-AA) core clinical criteria for mild cognitive impairment (MCI) due to AD, probable AD dementia or AD dementia
- Have a Clinical Dementia Rating (CDR) score of 0 (cognitively normal) or 0.5 (prodromal to moderate AD) at screening
- Have an Mini-Mental State Examination (MMSE) score 10-30 inclusive
- Have A# PET imaging demonstrating A# binding based on qualitative visual read at screening or using an acceptable historical PET scan (cognitively normal subjects will be assessed with A# PET at screening but will not be required to demonstrate A# binding).
- A brain MRI consistent with normal cognition or that supports a diagnosis of prodromal to moderate AD, with no evidence of other significant neurologic pathology. A previously acquired research MRI within the last 12 months may be used if deemed acceptable by the investigator and no significant clinically relevant changes have occurred since the prior MRI was obtained
- The subject has an appropriate study partner capable of participating in CDR assessment and, if necessary, of accompanying the subject
- For cognitively normal subjects only: History of at least one first degree relative with diagnosis of Alzheimer's disease (self-reported by the potential subject and/or confirmed by the study partner).

Exclusion Criteria:

- Current or prior history of any alcohol or drug abuse within the last 2 years
- Prior participation in other research protocols or clinical care in the last year in addition to the radiation exposure expected from participation in this clinical study, such that radiation exposure exceeds the effective dose of 50 millisievert (mSv), which would be above the acceptable annual limit established by the US Federal Guidelines
- Evidence of clinically significant gastrointestinal, cardiovascular, hepatic, renal, hematological, neoplastic, endocrine, alternative neurological, immunodeficiency, pulmonary, or other disorder or disease
- MRI evidence of cerebrovascular disease, infectious disease, space-occupying lesions, normal pressure hydrocephalus, or other central nervous system (CNS) disease
- Implants that have not been certified for MRI or history of claustrophobia in MRI, unless an acceptable previously acquired research MRI is available