ForPatients
by Roche

Alzheimer's Disease (AD)

A Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7812653 in Participants With Early Symptomatic Alzheimer's Disease (eAD)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07234942 2025-522101-37-00 BP45770

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:

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Single Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7812653 Following Intrathecal Administration in Participants With Early Symptomatic Alzheimer's Disease

Trial Summary:

This study aims to evaluate the safety, tolerability, immunogenicity, pharmacokinetics, and pharmacodynamics following administration of RO7812653 in participants with eAD.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT07234942 2025-522101-37-00 BP45770
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 75 Years	No

Inclusion Criteria:

- Probable AD dementia (consistent with National Institute on Aging and Alzheimer's Association (NIA-AA) core clinical criteria for probable AD dementia) [McKhann et al 2011] or Mild Cognitive Impairment (MCI) due to AD (consistent with the NIA-AA core clinical criteria for mild cognitive impairment due to AD) [Albert et al 2011]).

- Willingness and ability to complete all aspects of the study. The participant should be capable of completing assessments either alone or with the help of the study partner.
- Fluency in the language of the tests used at the study site.
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing (eyewear and hearing aids are permitted).
- If the participant is receiving symptomatic AD medications, a stable dosing regimen for at least 8 weeks prior to screening and until randomization is required.
- Agreement not to participate in other research studies for the duration of this study.

Exclusion Criteria:

- Any medical history or evidence of a condition other than AD that may affect cognition.
- Presence of any significant cerebral abnormalities that would contraindicate lumbar puncture, as assessed on MRI
- Any other significant cerebral abnormalities that the Investigator considers clinically significant
- History of schizophrenia, schizoaffective disorder, major depression or bipolar disorder.'
- Presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological medical conditions which are not stable and adequately controlled or which in the opinion of the investigator could affect the subject's safety in the study or interfere with the study assessments