ForPatients
by Roche

Alzheimer's Disease (AD)

A Study of Trontinemab in Cognitively Unimpaired Individuals at Risk for Progression to Symptomatic Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07717411 WN46072

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 III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Study of Trontinemab in Cognitively Unimpaired Individuals at Risk for Progression to Symptomatic Alzheimer's Disease

Trial Summary:

This study will evaluate the efficacy and safety of trontinemab in participants with biomarker evidence of Alzheimer's Disease (AD) pathology but with no cognitive or functional impairment, who are at risk for progression to mild cognitive impairment (MCI) due to AD or dementia due to AD.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT07717411 WN46072
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#55 Years & # 80 Years	No

Inclusion Criteria:

- Body weight of 150 kg or less
- Willingness and ability to complete all aspects of the study for the duration of the study
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing (eyewear and hearing aids are permitted)
- Cognitively and functionally unimpaired as defined by the protocol

- Availability of a study partner as defined by the protocol
- A plasma pTau217 level consistent with a high likelihood of future clinical progression

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition, including, but not limited to, frontotemporal dementia, dementia with Lewy bodies, vascular dementia, Parkinson disease, corticobasal syndrome, Creutzfeldt-Jakob disease, progressive supranuclear palsy, frontotemporal lobar degeneration (other than frontotemporal dementia), Huntington disease, normal pressure hydrocephalus, seizure disorder, delirium, or hypoxia
- Mild cognitive impairment (MCI; may be referred to as prodromal AD), or any form of dementia
- History or presence of clinically significant cerebrovascular disease
- History of severe, clinically significant (persistent neurologic deficit or structural brain damage) central nervous system (CNS) trauma
- History or presence of clinically significant intracranial mass
- History of schizophrenia, schizoaffective disorder, major depression, or bipolar disorder
- History or presence of any stroke with clinical symptoms within the past 12 months, or documented history within the last 12 months of an acute event that is consistent, in the opinion of the PI, with a transient ischemic attack
- At risk for suicide in the opinion of the investigator
- Substance abuse disorder within 12 months prior to screening (nicotine use is allowed)
- Any other medical conditions (e.g., cardiovascular, hepatic, renal disease) which are not stable and adequately controlled or which in the opinion of the investigator could affect the participant's safety in the study or interfere with the study assessments
- Uncontrolled hypertension
- Impaired hepatic function
- History or presence of any clinically significant hematological diseases
- Diagnosis of a wet age-related macular degeneration (AMD)
- Abnormal thyroid function
- Abnormally low serum levels of folic acid or vitamin B12 deficiency that are judged to be clinically significant and/or may impact cognition as per the investigator's judgment
- Current HIV, hepatitis B, or hepatitis C infection that has not been adequately treated in the opinion of the investigator
- History of malignancy
- Any previous administration of active immunotherapy (vaccine) that is being evaluated to prevent or postpone cognitive decline
- Any previous or current use of passive immunotherapy (immunoglobulin) or other long-acting biologic agent that is approved or under evaluation or has been evaluated to prevent or postpone cognitive decline
- Any other investigational treatment within 5 half-lives or 4 months prior to screening, whichever is longer
- Intravenous (IV) or subcutaneous immunoglobulin therapy within 5 half-lives or 4 months prior to baseline whichever is longer
- Anticoagulation medications at screening and there should be no plans to initiate any prior to or after randomization
- Any treatment with cholinesterase inhibitors
- Antipsychotic or neuroleptic medications within 3 months of screening, except as brief treatment for a non-psychiatric indication
- Individuals with chronic use of opiates or opioids, benzodiazepines, barbiturates, or hypnotics, antidepressants or medication to treat anxiety should be on a stable dose for at least 8 weeks before baseline

- Currently enrolled in an interventional study including those requiring investigational medicinal product (IMP) or involving any type of medical research that may interfere with study cognitive assessments
- Residence in a skilled nursing facility such as a convalescent home or long-term care facility