

Doença de Alzheimer (DA)

Um estudo de crenezumabe versus placebo para avaliar a eficácia e a segurança em participantes com doença de Alzheimer (DA) prodrômica a leve

CREAD 2: Estudo de Fase III, Multicêntrico, Randomizado, Duplo-cego, Controlado por Placebo, Grupos Paralelos, de Eficácia e Segurança de Crenezumabe em Pacientes com doença de Alzheimer Prodrômica à Leve.

Trial Status
Terminado

Trial Runs In
27 Countries

Trial Identifier
NCT03114657 2016-003288-20
BN29553

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Crenezumab in Patients With Prodromal to Mild Alzheimer's Disease

Trial Summary:

This randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of crenezumab versus placebo in participants with prodromal to mild AD. Participants will be randomized 1:1 to receive either intravenous (IV) infusion of crenezumab or placebo every 4 weeks (Q4W) for 100 weeks. The primary efficacy assessment will be performed at 105 weeks. The participants who do not enter open-label extension will enter for a long term follow-up period for up to 52 weeks after the last crenezumab dose (Week 153).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Eligibility Criteria:

Gender
All

Age
50 Years & # 85 Years

Healthy Volunteers
No

Inclusion Criteria:

- Weight between 40 and 120 kilograms (Kg) inclusive
- Availability of a person (referred to as the "caregiver") who in the investigator's judgment:
- Has frequent and sufficient contact with the participant to be able to provide accurate information regarding the participant's cognitive and functional abilities, agrees to provide information at clinic visits (which require partner input for scale completion), signs the necessary consent form, and has sufficient cognitive capacity to accurately report upon the participant's behavior and cognitive and functional abilities
- 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 (eye glasses and hearing aids are permitted)
- Evidence of the AD pathological process, by a positive amyloid assessment either on cerebrospinal fluid (CSF) amyloid beta 1-42 levels as measured on the Elecsys beta-amyloid(1-42) test system or amyloid PET scan by qualitative read by the core/central PET laboratory
- Demonstrated abnormal memory function at screening (up to 4 weeks before screening begins) or screening (FCSRT cueing index ≤ 0.67 AND free recall ≤ 27)
- Screening mini mental state examination (MMSE) score of greater than or equal to ($\geq$) 22 points and Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0
- Meets National Institute on Aging/Alzheimer's Association (NIAAA) core clinical criteria for probable AD dementia or prodromal AD (consistent with the NIAAA diagnostic criteria and guidelines for mild cognitive impairment (MCI))
- If receiving symptomatic AD medications, the dosing regimen must have been stable for 3 months prior to screening
- Participant must have completed at least 6 years of formal education after the age of 5 years

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition such as other dementias, stroke, brain damage, autoimmune disorders (e.g. multiple sclerosis) or infections with neurological sequelae.
- History of major psychiatric illness such as schizophrenia or major depression (if not considered in remission)
- At risk of suicide in the opinion of the investigator
- Any abnormal MRI findings, such as presence of cerebral vascular pathology, cortical stroke, etc or inability to tolerate MRI procedures or contraindication to MRI
- Unstable or clinically significant cardiovascular (e.g., myocardial infarction), kidney or liver disease
- Uncontrolled hypertension
- Screening hemoglobin A1c (HbA1C) $>8\%$
- Poor peripheral venous access
- History of cancer except:

If considered to be cured or If not being actively treated with anti-cancer therapy or radiotherapy

- Known history of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric, human, or humanized antibodies or fusion proteins