ForPatients
by Roche

Alzheimer's Disease (AD)Healthy Volunteers

A Single Ascending Dose Study to Investigate the Safety, Tolerability, Immunogenicity and Pharmacokinetics of Intravenously Administered RO7126209 in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04023994 BP41192

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 Single-Center, Randomized, Adaptive, Investigator/Subject Blind, Single Ascending Dose, Placebo-Controlled Phase I Study to Investigate the Safety, Tolerability, Immunogenicity and Pharmacokinetics of Intravenously Administered RO7126209 in Healthy Participants

Trial Summary:

Study BP41192 is a randomized, adaptive, placebo-controlled parallel group study to investigate the safety, tolerability, immunogenicity and pharmacokinetics of single-ascending intravenous (IV) doses of RO7126209 in healthy participants. RO7126209 is being developed for the treatment of Alzheimer's Disease.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04023994 BP41192
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years & # 40 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Healthy status is defined by the absence of evidence of any active or chronic disease following a detailed medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, ophthalmologic examination, hematology, blood chemistry, coagulation, serology, and urinalysis.

- Body mass index (BMI) of 18-30 kg/m2 inclusive
- During the treatment period and until the final follow up visit, agreement to: (1) Remain abstinent or use contraceptive measures such as a condom plus an additional contraceptive method that together result in a failure rate of <1% per year, with a partner who is a woman of childbearing potential. (2) With pregnant female partner, remain abstinent or use contraceptive measures such as a condom to avoid exposing the embryo. (3) Refrain from donating sperm from Day 1 of the study until 90 days after last dose.

Exclusion Criteria:

- Concomitant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the participant in this study.
- History of any clinically significant gastrointestinal, renal, hepatic, broncho-pulmonary, neurological, psychiatric, cardio-vascular, endocrinological, ophthalmologic, hematological or allergic disease, metabolic disorder, cancer or cirrhosis.
- Any suspicion or history of alcohol abuse and/or suspicion of regular consumption of drug of abuse within the last 5 years.
- Positive result on hepatitis B (HBV), hepatitis C (HCV), or human immunodeficiency virus (HIV) 1 and 2.
- History or presence of clinically significant ECG abnormalities or cardiovascular disease.
- Clinically-significant abnormalities in laboratory test results.
- Any major illness within one month before the screening examination or any febrile illness within one week prior to screening and up to first dose administration.
- Impaired hepatic function as indicated by screening aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >=1.5 x the upper limit of normal (ULN) or abnormal total bilirubin unless due to Gilbert's disease.
- Any clinically relevant history of hypersensitivity or allergic reactions, either spontaneous or following drug administration, or exposure to foods or environmental agents.
- History of hypersensitivity to biologic agents or any of the excipients in the formulation.
- History of raised intra-cerebral pressure or vertebral joint pathology
- Use of prohibited medication or herbal remedies as described in the section of concomitant medications
- Prior administration of gantenerumab (RO4909832)
- Any vaccination within two months prior to Day 1
- Participation in an investigational drug medicinal product or medical device study within 30 days before screening or within seven times the elimination half-life if known, whichever is longer.
- Participants who regularly smoke more than 5 cigarettes daily or equivalent and are unable or unwilling not to smoke during the in-house period.
- Donation or loss of blood over 500 mL within three months prior to Day 1 and donation of blood for the duration of the study until follow-up.
- Evidence of clinically significant brain magnetic resonance imaging (MRI) findings, including lacunar infarct, territorial infarct or macroscopic hemorrhage, microbleed or area of leptomeningeal hemosiderosis, or deep white matter lesions corresponding to an overall Fazekas score of # 2.
- Claustrophobia, presence of pacemakers, aneurysm clips, artificial heart valves, ear implants, or foreign metal objects in the eyes, skin, or body that would contraindicate an MRI scan.