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A study to evaluate the effects of RO7269162 on the body following oral administration in presymptomatic gene mutation carriers and non-carriers from the same kindred in Alzheimer's Disease

Submission date 02/12/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/12/2022	**Overall study status** Completed	
Last Edited 10/10/2025	**Condition category** Nervous System Diseases	

Plain English summary of protocol

Background and study aims:
RO7269162 is an experimental drug being developed for the possible treatment of Alzheimer's Disease (AD). AD is a slowly developing disease of the brain that affects memory and other brain functions. Health Authorities have not approved RO7269162 for the treatment of AD or any other disease.
The main purpose of this study is to investigate the effect of RO7269162 on biological molecules found in the blood that are indicative of a disease (biomarker) in participants who are carriers of an altered/changed gene (mutation).

Who can participate?
People between the ages of 18 to 25 years (both inclusive)

What does the study involve?
Participants will have to be a part of this study for approximately 14 to 15 weeks. This study will have four parts:
1. Screening Period: Participants will undergo certain screening tests and/or procedures to make sure that they are eligible to take part in this study. Participants will have a screening visit up to 12 weeks before the study starts.
2. In-house Period: Participants will be admitted to the clinical site in the afternoon few days before the study medication is administered and they will have to stay in the clinic for a stipulated period of time. Participants will be allowed to go back home no earlier than 72 hours after the last study medication administration.
During this period participants will receive RO7269162 by mouth for multiple days.
3. Ambulatory visit: Participants will have to return to the clinic for an ambulatory visit on Day

12. This visit is for checking on the participants after treatment is finished.
4. Follow-up visit: Participants will have to return to the clinic 8 to 10 days after the last dosing for a final safety follow-up visit.

What are the possible benefits and risks of participating?
Participants may not receive any health benefits from the study drug. However, the information learned in this study will help in the further development of RO7269162 and may benefit patients with AD in future.
Reasonable travel costs, food costs and other reasonable out of pocket expenses will be refunded to the participants.
Participants may experience side effects from the treatments or procedures in this study. Side effects can vary from mild to serious and may be different from person to person. As RO7269162 is a new experimental drug with limited testing in humans, not all the side effects that could occur are known at this time.
Muscle aches in the legs, headache, nausea and light-headedness are the known side effects of RO7269162.
There may be a risk in exposing an unborn child to the study treatment, and not all potential consequences are known at this time. Women and men must take precautions to avoid exposing an unborn child or a breastfed baby to the study treatment. Participant or their partner who are pregnant, currently breastfeeding or are planning to become pregnant during the study cannot take part in this study.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
July 2022 to October 2024

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
BP44161

Study information

Scientific Title
A single-center, adaptive, repeated dose, phase I study to investigate the pharmacodynamics of RO7269162 following oral administration in presymptomatic carriers and in non-carriers of a genetic mutation from the same kindred in autosomal-dominant Alzheimer's Disease

Study objectives
The purpose of this study is to assess the effect of multiple doses of RO7269162 on pharmacodynamic (PD) biomarkers in carriers of a specific genetic mutation. The study also aims to characterize the pharmacokinetic-pharmacodynamic (PKPD) relationships of RO7269162 in carriers of a genetic mutation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/11/2022, El Hospital Con Alma Pablo Tobón Uribe, Comité De Investigaciones y Ética En Investigaciones (Calle 78B No. 69-240, Medellín - Colombia; +57 604 445 90 00; comiteinvestigaciones@hptu.org.co)

Primary study design
Interventional

Study design
Phase I single-centre repeated dose adaptive study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autosomal-dominant Alzheimer's disease

Interventions
Cohort 1: Participants will receive RO7269162, at dose level 1, orally, for up to 7 days
Cohort 2: Participants will receive RO7269162, at dose level 2, orally, for up to 7 days

Follow up to day 15.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7269162

Primary outcome(s)
1. Time course of PD biomarkers measured using blood samples collected at multiple timepoints from baseline (Day -2) up to follow-up visit at Day 15
2. Change in PD biomarkers measured using blood samples at multiple timepoints from baseline (Day -2) up to follow-up visit at Day 15
3. Relationship between RO7269162 exposure and PD responses related to biomarkers measured using blood samples collected at multiple timepoints from baseline (Day -2) up to follow-up visit at Day 15

Key secondary outcome(s)
1. Maximum observed plasma concentration (Cmax) of RO7269162 (and its metabolite(s) as appropriate) measured using blood samples collected at multiple timepoints on Days 1 and 7
2. Area under the plasma concentration-time curve (AUC) from zero up to 24 hours (h) (AUC0-24h) of RO7269162 (and its metabolite(s) as appropriate) measured using blood samples collected at multiple timepoints on Days 1 and 7
3. Number of participants with adverse events (AEs) and severity of AEs from signing of Informed Consent Form up to follow up visit at Day 15

Completion date
07/10/2024

Eligibility

Key inclusion criteria
1. 18 to 25 years of age inclusive
2. Membership in gene mutation carrier kindred. Gene mutation carrier or non-carrier status will have been confirmed prior to or during the screening period
3. Body mass index (BMI) of 18-32 kilograms per metre square (kg/m^2) inclusive

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Any clinically relevant finding, condition or disease detected during the medical interview /physical examination at screening or Day -1.
2. History or evidence of any medical condition capable of significantly altering the absorption, metabolism, or elimination of drugs, including surgical history affecting gastric motility or altering the gastrointestinal tract.
3. History of convulsions
4. Participants who, in the investigator`s judgment, pose a suicidal or homicidal risk
5. Vaccination within 6 weeks prior to Day 1 including influenza and/or SARS-CoV-2/COVID-19 vaccination.
6. Positive result on human immunodeficiency virus 1 (HIV1) and HIV2, hepatitis C virus (HCV) or hepatitis B (HBV).
7. Participants who test positive for acute respiratory syndrome coronavirus 2 (SARSCoV-2) on admission to the study site

Date of first enrolment
11/03/2024

Date of final enrolment
23/09/2024

Locations

Countries of recruitment
Colombia

Study participating centre
Grupo de Neurociencias de Antioquia de la Universidad de Antioquia
Carrera 51 a # 62-42 Piso 3 Torre B
Medellín, Antioquia
Colombia
0500

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available