

A study investigating the effect of several doses of itraconazole on how the body processes RO7269162, a new compound in clinical development for the treatment of Alzheimer's disease

Submission date 15/05/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/05/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Alzheimer's disease is a form of dementia (memory loss). This study is testing a medicine called RO7269162. It is being developed to treat Alzheimer's disease. RO7269162 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7269162 for the treatment of Alzheimer's disease. This study aims to test how safe RO7269162 is. Also, it aims to understand what happens to RO7269162 once it is in the body and if there are any changes when it is taken with another medicine called itraconazole at the same time.

Who can participate?

Healthy participants (males and females) of 18 to 55 years of age and a body mass index (BMI) of 18 to 30 kilogram per meter squared (kg/m²) can take part in the study. Participants may not be able to take part in this study if they smoke more than 5 cigarettes per day, need to follow certain dietary restrictions, or are likely to take medication during the study. Participants who are pregnant, or currently breastfeeding cannot take part in the study.

What does the study involve?

Participating in the study will take up to 9 weeks from screening to follow-up. Participants will be screened to check if they can participate in the study. The screening period will take place from 28 days to 2 days before the start of treatment.

Everyone who joins this study will receive the study drug in 2 periods. Participants will be given RO7269162, as a pill by mouth, on Day 1 of Period 1 and Period 2. Participants will also be given itraconazole, as a pill by mouth starting 3 days before Day 1 of Period 2 up to Day 9 of Period 2.

During this study, the study doctor will see participants regularly during the in-house periods (overnight stays at the clinic) and ambulatory visits (short visits during a day at the clinic). The first in-house period lasts 6 days, followed by 1 ambulatory visit, then Period 2 starts, with 14 days in-house, followed by 2 ambulatory visits. Participants will then have a follow-up visit 2 to 6 days after completing the second study treatment period, during which the study doctor will check on the participant's well-being.

Participants have the right to stop the study drug and leave the study at any time if they wish to do so.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

What are the possible benefits and risks of participating?

Taking part in the study may or may not make participants feel better. However, the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participants. However, these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options for treatment.

Risks associated with the study

Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

RO7269162

Participants will be told about the known unwanted effects of RO7269162 and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include headache, changes to the skin, frequent watery stools (diarrhoea), vomiting, queasy feeling in the stomach that gives the sensation of wanting to vomit (nausea), the feeling of spinning, being unsteady and losing balance (dizziness), and back pain.

Itraconazole

Known unwanted effects include stomach ache, nausea, and headache.

The study medicine may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

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?

April 2024 to September 2026

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

global.trial_information@roche.com

Contact information

Type(s)

Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

2024-510732-52-00

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

BP45228

Study information

Scientific Title

A single-center, open-label, two-period study to investigate the effect of multiple-dose itraconazole, a strong CYP3A inhibitor, on the pharmacokinetics of a single dose of RO7269162 in healthy participants

Study objectives

The main purpose of this study is to assess the effect of multiple doses of itraconazole on the single-dose pharmacokinetics (PK) of RO7269162 in healthy participants.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/05/2024, Stichting Beoordeling Ethiek Biomedisch Onderzoek (Weiersstraat 1C, Assen, 9401 ET, Netherlands; +31 0592 40 58 71; info@stbebo.nl), ref: Nil known

Study design

Phase I single-center non-randomized open-label single-sequence two-period drug-drug interaction study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthy volunteer

Interventions

Participants will receive a single dose of RO7269162, orally on Day 1 of Period 1. After an interval of at least 7 days, participants will receive itraconazole, orally, once daily, from Day -3 to Day 9 of Period 2. Participants will also receive a single dose of RO7269162, orally on Day 1 of Period 2.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

RO7269162, Itraconazole

Primary outcome(s)

1. Maximum observed plasma concentration (C_{max}) of RO7269162 determined using blood samples collected at pre-dose and multiple time-points post-dose from Day 1 up to Day 7 of Period 1 and Day 1 up to Day 14 of Period 2
2. Time to maximum plasma concentration (T_{max}) of RO7269162 determined using blood samples collected at pre-dose and multiple time-points post-dose from Day 1 up to Day 7 of Period 1 and Day 1 up to Day 14 of Period 2
3. Area under the plasma concentration-time curve from time zero up to the last measurable concentration (AUC_{last}) of RO7269162 determined using blood samples collected at pre-dose and multiple time-points post-dose from Day 1 up to Day 7 of Period 1 and Day 1 up to Day 14 of Period 2

4 Area under the plasma concentration-time curve from time zero extrapolated to infinity (AUC_{inf}) of RO7269162 determined using blood samples collected at pre-dose and multiple time-points post-dose from Day 1 up to Day 7 of Period 1 and Day 1 up to Day 14 of Period 2

Key secondary outcome(s)

1. Number of participants with adverse events (AEs) and severity of AEs determined according data captured on the electronic case report forms (eCRF) from Screening to Follow-up (up to approximately 9 weeks)
2. Plasma Concentration of itraconazole determined using blood samples collected at pre-dose and multiple time-points post-dose from Day -3 to Day 14 of Period 2

Completion date

23/07/2024

Eligibility

Key inclusion criteria

1. Body mass index (BMI) of 18 to 30 kilograms per metre squared (kg/m²) inclusive (at screening)
2. Participants who are overtly healthy determined by no clinically significant findings from medical history, 12-lead electrocardiogram (ECG), or vital signs

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

All

Key exclusion criteria

1. History or presence of any clinically significant cardiovascular, bronchopulmonary, hepatic, renal, gastrointestinal, endocrinological, hematological, neurological, psychiatric, genitourinary, metabolic disorders, allergic diseases, cancer, or cirrhosis
2. History or evidence of any medical condition capable of significantly altering the absorption, metabolism, or elimination of drugs
3. Surgical history of the gastrointestinal tract affecting gastric motility or altering the gastrointestinal tract
4. History of malignancy in the past 5 years
5. Known active or uncontrolled bacterial, viral, fungal, mycobacterial infection, or other

Infection

6. Participation in an investigational drug study involving any therapeutic monoclonal antibody
7. Positive test for drugs of abuse or alcohol
8. Positive result on human immunodeficiency virus (HIV) 1 and HIV2, hepatitis C virus (HCV) or hepatitis B virus (HBV)
9. Participants who have donated over 500 milliliters (mL) of blood or blood products or had significant blood loss within 3 months before screening.

Date of first enrolment

07/06/2024

Date of final enrolment

28/06/2024

Locations

Countries of recruitment

Netherlands

Study participating centre

ICON

Van Swietenlaan 6

Groningen

Netherlands

9728 NZ

Sponsor information

Organisation

F. Hoffmann-La Roche Ltd

Funder(s)

Funder type

Industry

Funder Name

F. Hoffmann-La Roche

Alternative Name(s)

Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

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