ForPatients
by Roche

Alzheimer's Disease (AD)

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

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	2024-510732-52-00 ISRCTN84512041 BP45228

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, OPEN-LABEL, TWO-PERIOD STUDY TO INVESTIGATE THE EFFECT OF MULTIPLE DOSE ITRACONAZOLE, A STRONG CYP3A INHIBITOR, ON THE PHARMACOKINETICS OF A SINGLE 30 MG DOSE OF RO7269162 IN HEALTHY PARTICIPANTS.

Trial Summary:

This study is testing a medicine called RO7269162. It is being developed to treat Alzheimer’s disease, a form of dementia (memory loss). 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.

This study was divided in two parts, called Part 1 and Part 2. Participants joined both parts of the study. During Part 1 , the participants took a single dose of RO7269162 orally as a capsule, on a full stomach.

During Part 2, the participants took itraconazole orally as a capsule, once a day for 12 consecutive days, on a full stomach. On the 4th day, participants also took a single dose of RO7269162, orally as a capsule, about an hour after taking itraconazole.

Eighteen participants joined the study and one participants left the study at the end of Part 1. So, seventeen participants only joined Part 2.

Sponsor	Phase
F. Hoffmann-La Roche Ltd	**Phase I**

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	**18 to 55 Years of age**	**Yes**

1. Why is this study needed?

This study is testing a medicine called RO7269162. It is being developed to treat Alzheimer's disease, a form of dementia (memory loss).

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.

2. Who can take part in the study?

Healthy people (males and females) of 18 to 55 years of age and a body mass index (BMI) of 18 to 30 kg/m2 can take part in the study.

People 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.

People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

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

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.

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 after 2 to 6 days after completing the second study treatment period, during which study doctor will check on the participant's well-being.

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

4. What are the main results measured in this study?

The main clinical study endpoint (the main result obtained from the study assessments) is the measure of study medicine levels in the body when taken alone and when taken together with another medicine, itraconazole. Other key results in the study include the number and seriousness of any side effect of RO7269162, number of abnormal laboratory results, number of abnormal vital and cardiac parameters when it is taken alone or in combination with itraconazole.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But participation will help the investigators to increase the knowledge about the effects of RO7269162 and help in the search for a better treatment of Alzheimer's disease.

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, diarrhoea, vomiting, nausea, dizziness, and back pain.

Itraconazole

Known unwanted effects include stomach ache, feeling sick (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.

Inclusion Criteria:

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

Exclusion Criteria:

- History or presence of any clinically significant cardiovascular, bronchopulmonary, hepatic, renal, gastrointestinal, endocrinological, hematological, neurological, psychiatric, genitourinary, metabolic disorders, allergic diseases, cancer, or cirrhosis
- History or evidence of any medical condition capable of significantly altering the absorption, metabolism, or elimination of drugs
- Surgical history of the gastrointestinal tract affecting gastric motility or altering the gastrointestinal tract
- History of malignancy in the past 5 years
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial infection, or other Infection
- Participation in an investigational drug study involving any therapeutic monoclonal antibody
- Positive test for drugs of abuse or alcohol
- Positive result on human immunodeficiency virus (HIV) 1 and HIV2, hepatitis C virus (HCV) or hepatitis B virus (HBV)
- Participants who have donated over 500 milliliters (mL) of blood or blood products or had significant blood loss within 3 months before screening.