ForPatients
by Roche

Parkinson's Disease (PD)

A study to test the biological properties of RO7568282 and whether it is safe in healthy participants and participants with Parkinson’s disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	2024-511110-21-00 BP45361

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 phase I randomized, investigator/participant blind, adaptive, single ascending dose and multiple ascending dose, placebo-controlled, parallel study to investigate the safety, tolerability, pharmacokinetics (including the effect of food), and pharmacodynamics of RO7568282 following oral administration in healthy participants and in participants with Parkinson’s disease (open-label)

Trial Summary:

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

2024-511110-21-00 BP45361
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18-64 years & 65+ years	Yes

1. Why is this study needed?

This study is testing a medicine called RO7568282. It is being developed to treat Parkinson’s disease. Parkinson’s disease is a chronic disease of the nervous system (mostly the brain) that gets worse over time. Currently available treatments address symptoms and not the cause of Parkinson’s disease progression. Some evidence suggests that people with Parkinson’s disease may have more inflammation in the brain, which may be one of the reasons why Parkinson's disease gets worse over time. A key component of this inflammation is a protein called NLRP3. The study medicine

(RO7568282) is designed to block this protein which could potentially slow the progression of Parkinson's disease. This study aims to:

- test how safe RO7568282 is at different doses (given either only once or multiple times),
- understand the impact of food on RO7568282,
- understand what happens to RO7568282 once it is in the body,
- look at the effect of RO7568282 on specific proteins and other components in the blood and fluid around the brain and spine.

RO7568282 is an experimental medicine. This means health authorities (like European Medicines Agency) have not approved RO7568282.

2. Who can take part in the study?

Healthy people (males / females) of 18-45 years of age (Part 1a), 18-55 years of age (Part 1b), 18-64 years of age (Part 2), or people with early-stage Parkinson's disease of 40-75 years of age (Part 3) can take part in the study. In Part 3, females can only take part if they have gone through menopause (i.e., the time in a female person's life when they have been at least 12 months without a menstrual period).

People may not be able to take part in this study if they have certain medical conditions such as a condition that affects how the body processes drugs (for example, stomach or intestine surgery), a major illness within 1 month of the start of the study or high pulse or blood pressure.

3. How does this study work?

This clinical study is recruiting healthy people (Part 1a, Part 1b and Part 2) and participants with Parkinson's disease (Part 3). People will be screened to check if they are able to participate in the study. The screening period will take place as follows before the start of treatment:

Part 1a and Part 2 – 28 to 3 days
Part 1b – 2 days
Part 2 – 28 to 3 days
Part 3 – 28 days

Part 1 will evaluate the safety, tolerability and drug levels after a single dose. It consists of Part 1a and Part 1b:

Part 1a will evaluate at least 6 dose levels (also called groups) of the study medicine. It will be placebo controlled. A placebo is a substance that looks like a study medicine but contains no active medication. Everyone in Part 1a will be randomly assigned to one of the following treatment groups: the study medicine or placebo. This means that

participants are put into a group by chance (like tossing a coin or rolling a dice). This is a double-blinded study. Neither the study participants nor the team conducting the study will know which treatment is being given until the study is over, with the exception of the pharmacist who prepares the study treatment. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

Part 1b will evaluate the effect of food on a single administration of the study medicine, and no placebo will be used.

Part 2 will evaluate the safety, tolerability and study medicine levels of 4 doses in the body after multiple administration of the study medicine. It will be placebo controlled. It will be double-blinded.

Part 3 will evaluate if the study medicine at different dose levels has any effects (good or bad), what happens to the study medicine once it is in the body, and what the study medicine does to the body and the disease. Everyone in Part 3 will receive the study medicine for about four weeks.

During this study, the study doctor will meet with or talk to the participants on a regular basis. They will see how well the treatment is tolerated by the participants and identify any unwanted effects that participants may have. After completing study treatment, all participants will have a final follow-up visit during which the study doctor will check on their 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?

In Part 1a, Part 2 and Part 3 of the study, the main study endpoint (the main results measured in the study) is to see how safe the study medicine is. In Part 1b of the study, the main study endpoint is to measure the effect of food on the absorption and elimination of study medicine from the body, additionally the safety of the study medicine will be measured. Other key results measured in the study include:

Part 1a, Part 2 and Part 3 of the study will also measure,

- Blood levels of study medicine in the body
- the effect of the study medicine on specific proteins and other components in the blood
- the effect of the study medicine on specific proteins and other components in the fluid around the brain and spine (Part 3 only)

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

Participants will not benefit from this study, beyond having a general medical check-up. But their participation will help the investigators to increase the knowledge about the effects of the study medicine and help in the search for a better treatment of specific diseases.

It may not be fully known at the time of the study how safe and how well the study medicine works. The study involves some risks to the participant.

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.

Risks associated with the study medicine:
Participants may have unwanted effects of the medicine 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. At the start of Part 3 of the study, the study medicine will have been safely tested in several healthy participants in the by then already completed Part 1a, Part 1b and Part 2 of the study.

However, the unwanted effects of this medicine are not yet fully known.

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.