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Neurodevelopmental Disorder

A study to investigate the effect of enzyme inhibition on the bodily processing of RO6953958 in healthy participants

A non-randomized, open-label, single-sequence, two-period phase I study to investigate the effect of CYP3A inhibition on the pharmacokinetics of RO6953958 in healthy participants

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	BP43293

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is a Phase 1 study, looking at how the study drug (RO6953958) works in the human body and the safety of this drug in healthy volunteers. This trial does not test if the drug helps to improve health. The main purpose of this study is to determine if a drug interaction exists when the study drug (RO6953958) and itraconazole are taken together. A drug interaction means one drug alters how another drug works or how it is processed in the body. A drug interaction may cause one of the drugs to not work very well or have worse side effects. This study will look at:

- effect of itraconazole and its metabolites (drug breakdown byproducts) on the pharmacokinetics (PK, the amount of study drug in the blood stream and how long the body takes to get rid of it) of a single dose of RO6953958 and its metabolites (study drug breakdown byproducts) in healthy participants.
- how safe and tolerable a single dose of RO6953958 is, when taken alone and when co-administered with itraconazole in healthy participants.
- pharmacokinetics (PK) of multiple doses of itraconazole and its metabolites in healthy participants when given alone and when co-administered with RO6953958.
- taste of RO6953958.
- genetic variations play a role in how a RO6953958 is metabolized when given in combination with itraconazole.

BP43293
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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Male and Female	18 to 55 years	Yes

Who can participate? Healthy people aged between 18 to 55 years old.

What does the study involve?
Participants may be asked to be in the study for up to 9 weeks. This includes: 1) Screening Period (questions and tests to see if participants are eligible for the study) that will occur up to 28 days before the beginning of the study period. Participants will not be confined to the study center during the Screening period; 2) Two in-house Study Treatment Periods. Participants will be confined to the study center for up to 5 days and 4 nights for the first Study Treatment Period and up to 14 days and 13 nights for the second Study Treatment Period; 3) 5 ambulatory (out-patient) visits. Three of these visits will occur between the first in-house period and the second in-house period, and two of these visits will occur after the second in-house period; 4) Follow-up Visit (Day 18) approximately 14 days after the last dose of RO6953958.
There will be pharmacogenomic testing involving human genes. Pharmacogenomics is the study of differences in how our bodies respond to or handle medicines. The participant's sample will be tested to see if there are genetic variations in the participant's body's proteins that may affect how the study drug is absorbed, distributed, broken down, and removed from the participant's body. The genetic testing done in this study focuses on finding out if a gene (or combinations of genes) can be used to predict the response to RO6953958.

What are the possible benefits and risks of participating?
There is no particular benefit in participating in this research. Participants' health may or may not improve in this study, but the information that is learned may help other people who have a related medical condition in the future.
There are some most common side effects related to RO6953958, reported are headache and sleepiness. To date, there have been no safety concerns and participants have tolerated RO6953958 well.

Potentially related side effects could be a decrease in blood pressure and may inhibit platelet aggregation, resulting in bleeding. But no relevant blood pressure changes or bleeding events have been reported in the previous clinical trial with RO6953958 (see above).
There may be other risks that are unknown. These include Itraconazole-related risks such as upset stomach nausea, vomiting, rash; allergic reaction Risks; drug interaction risks (drugs working with or against each other); other potential risks including blood draw and intravenous injection, ECG Risks, fasting Risks, and other unknown ones.

Where is the study run from?
PRA Health Sciences (USA)

When is the study starting and how long is it expected to run for?

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April 2021 to December 2021

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

Who is the main contact?
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