ForPatients
by Roche

Schizophrenia

A study to evaluate the safety, tolerability, processing by the body and mechanism of action of multiple doses of ralmitaront with a single dose of risperidone administered to healthy participants

A single-center, single-sequence, open-label, two-period study to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of the combination of multiple doses of ralmitaront with a single dose of risperidone in healthy subjects

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	BP43026

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

Trial Summary:

The main aim of this study is to determine if a drug interaction exists when the study drug (ralmitaront) and risperidone are taken together. A drug interaction means one drug alters how another drug works or how it is processed in the body. Ralmitaront is an investigational drug being developed as a treatment for psychotic and affective disorders, including schizophrenia.

BP43026
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
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?
The study duration is up to 8 weeks. This includes a screening period for up to 28 days before the beginning of the study period; an in-house period consisting of two study treatment periods staying at the study center for up to 20 days or 19 nights; and a follow-up visit for 14 days after the last dose of ralmitaront on Day 14. Participants will be asked

to come to the study center about three times, if not needed for additional visits. When taking the research drug, the sponsor, study doctor and staff will know what participants are receiving at all times openly.

Study Treatment Period 1:
On Day 1 of the study treatment period, participants will receive a single oral (by mouth) dose of risperidone 0.5 mg or 1 mg (2 x 0.5 mg tablets). The study drug will be administered with a cup of water. Beginning on Day 2 and continuing through Day 5, participants will undergo a washout period, a period of time where participants will not take any study drug.

Study Treatment Period 2:
On Days 6 through 15, participants will receive a daily dose of ralmitaront. Participants will take the capsules by mouth with a cup of water. On Day 14, participants will receive risperidone 0.5 mg or 1 mg (2 x 0.5 mg tablets) 30 minutes after taking the daily dose of ralmitaront. Samples collected for study-related tests will be stored until the study results have been reported. If participants withdraw from the study, any sample collected prior to participant's withdrawal may still be tested, unless participants specifically ask for their samples to be destroyed or local laws require the destruction of the samples.

What are the possible benefits and risks of participating?
The participants' health may or may not improve in this study, but the information collected may help other people who have a similar medical condition in the future. There have been ralmitaront and risperidone related risks reported involving headache, dizziness, fatigue, skin irritation, diarrhea/soft feces, nausea, abdominal pain, musculoskeletal chest pain, high blood pressure, respiratory viral infection, palpation, abnormal blood biochemistry, difficult or painful swallowing, dry mouth, weight gain, increased appetite, common cold, fever and Parkinson-like symptoms (tremors, unstable balance, rigidity). There could also be risks of allergic reactions including drug interaction risks (medicines working with or against each other) and risks specific to lumbar puncture.

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

When is the study starting and how long is it expected to run for?
September 2021 to April 2022

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

Who is the main contact?
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