ForPatients
by Roche

Autism Spectrum Disorder

A Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Food Effect of RO6953958 in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04475848 2019-004486-41 BP41695

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 Randomized, Investigator- /Subject-blind, Single- and Multiple-ascending Dose, Placebo-controlled Study to Investigate Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Food Effect of RO6953958 (Including RO6953958 Effect on Midazolam) Following Oral Administration in Healthy Male Participants

Trial Summary:

This study will evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single- and multiple-ascending doses (SAD (Part 1) and MAD (Part 2)) and food effect (FE) of RO6953958 following oral administration in healthy male participants. Part 3 (Drug-drug interaction (DDI)) will assess the safety, tolerability, and effect of RO6953958 on the PK of the cytochrome P450 (CYP) 3A substrate midazolam.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04475848 2019-004486-41 BP41695
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years & # 55 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Body mass index (BMI) within 18 to 31 kg/m2
- During treatment and for at least 14 days after the last dose to remain abstinent

- Refrain from donating sperm for at least 14 days after last dose
- Part 2 (MAD) only - Participants must be prepared to collect a sleep log and wear an actigraphy device the week before participation in the study. Participants must also have scored 5 or less on the Pittsburgh Sleep Quality Index (PSQI), less than 13 on the Epworth sleepiness scale (ESS), and not be considered an extreme morning or evening type according to the morningness-eveningness questionnaire (MEQ) at screening to be eligible.

Exclusion Criteria:

- History or evidence of any medical condition potentially altering the absorption, metabolism, or elimination of drugs
- History of any clinically significant gastrointestinal, renal, hepatic, bronchopulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological, or allergic disease, sleep disorders (Part 2 [MAD] only), unexplained syncope (within 12 months prior to screening), metabolic disorder, cancer, or cirrhosis
- Use of any psychoactive medication, or medications known to have effects on central nervous system (CNS), or blood flow
- History of convulsions
- History of clinically significant hypersensitivity (e.g., drugs, excipients) or allergic reactions
- Abnormal blood pressure (BP) and pulse rate
- Presence of orthostatic hypotension
- History or presence of clinically significant ECG abnormalities or cardiovascular disease
- Current or chronic history of liver disease or known hepatic or biliary abnormalities
- Known active or any major episode of infection within 4 weeks prior to the start of drug administration
- Participants who test positive for acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- Have used or intend to use over-the-counter (OTC) or prescription medication including herbal medications within 30 days prior to dosing
- Positive test for drugs, abuse of alcohol, human immunodeficiency virus (HIV), hepatitis B or hepatitis C virus (HCV), presence of hepatitis B surface antigen (HBsAg), or positive hepatitis C antibody test
- Inability or unwillingness to fully consume standardized breakfast at Day 1
- Part 2 (MAD) only - Participants who have issues sleeping or participants who have travelled across 2 or more time zones in the past month.
- Part 2 (MAD) only - Participants who cannot produce sufficient saliva for study assessments
- Participants who have donated more than 500 mL of blood or blood products or had significant blood loss within 3 months prior to screening
- Have a history of clinically significant back pain, back pathology, and/or back injury that may predispose to complications from, or technical difficulty with, lumbar puncture
- Complications that would lead to difficulty in obtaining a lumbar puncture
- Part 3 (DDI) only - History of hypersensitivity to benzodiazepines (including midazolam) or its formulation ingredients