ForPatients

by Roche

Autism Spectrum Disorder

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

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 Status Trial Runs In Trial Identifier

Completed 1 Countries NCT04475848 2019-004486-41

BP41695

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 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 Male	Age >=18 Years & <= 55 Years	Healthy Volunteers Accepts Healthy Volunteers	