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