ForPatients

by Roche

Autism Spectrum Disorder

A Study to Investigate the Pharmacokinetics, Safety, and Tolerability of Balovaptan in Children With Autism Spectrum Disorder

Trial Status	Trial Runs In	Trial Identifier
Terminated	2 Countries	NCT04049578 WP40877

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 was a Phase Ib, multicenter, open-label study in children 2-4 years old with autism spectrum disorder (ASD) to investigate the pharmacokinetics, safety, and tolerability of an oral dose of balovaptan once a day (QD). The study was to consists of a 6-week treatment period to evaluate the pharmacokinetics of balovaptan in 2 to 4 year old children followed by an optional extension period of 48 weeks.

Hoffmann-La Roche Sponsor	Phase 1 Phase	
NCT04049578 WP40877 Trial Identifiers		
Eligibility Criteria:		
Gender All	Age >=2 Years & <= 4 Years	Healthy Volunteers