ForPatients
by Roche

Beta-Thalassemia

A Study of Bitopertin (RO4917838) in Adults With Non-Transfusion-Dependent (NTD) Beta-Thalassemia

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03271541 2016-004799-23 BP39642

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 proof-of-mechanism study is being performed to investigate the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of multiple oral doses of bitopertin in adults with NTD beta-thalassemia. This study consists of two parts: Part 1 - The main study - 16 weeks in total: Participants will undergo a 6-week dose-escalation period followed by 10 weeks of treatment at the attained target dose. Part 2 - Open Label Extension (OLE) - up to an additional 12 months. Participants will be given the option to enroll into the OLE once the 16-week treatment of Part 1 has been completed. Participants who decide not to enroll in the OLE, at the end of Part 1 will enter a 6-week follow-up period.

Hoffmann-La Roche	**Phase 2**
Sponsor	Phase

NCT03271541 2016-004799-23 BP39642
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 55 Years	No