ForPatients
by Roche

Juvenile Idiopathic Arthritis

A Study of Decreased Dose Frequency in Participants With Systemic Juvenile Arthritis Who Experience Laboratory Abnormalities During Treatment With RoActemra/Actemra (Tocilizumab)

Trial Status	Trial Runs In	Trial Identifier
Completed	9 Countries	NCT01734382 2012-000444-10 WA28029

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

PART1 Participants in Part 1 (Run-in-Phase) of study will receive Tocilizumab (TCZ) (RoActemra/Actemra) 12 milligrams per kilogram (mg/kg) or 8 mg/kg intravenously (IV) every 2 weeks (Q2W) for up to 24 weeks. Participants who experience a laboratory abnormality during part 1 may be eligible to move into Part 2 of the study. PART 2 This open-label Phase IV study will evaluate the efficacy, safety, pharmacokinetics, pharmacodynamics and immunogenicity of RoActemra/Actemra (tocilizumab) in reduced dose frequency in participants with adequately controlled systemic juvenile idiopathic arthritis who have experienced a laboratory abnormality on twice weekly RoActemra/Actemra dosing, that has since resolved. Participants will receive RoActemra/Actemra 12 mg/kg or 8 mg/kg intravenously every 3 weeks. After 5 consecutive infusions, participants who experience an event of neutropenia, thrombocytopenia or liver enzyme abnormality will move to every 4 weeks RoActemra/Actemra administration. Anticipated time on study treatment is 52 weeks.

Hoffmann-La Roche Sponsor	**Phase 4** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=2 Years & <= 17 Years	No