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	10 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 tocilizumab in reduced dose frequency in participants with adequately controlled systemic juvenile idiopathic arthritis who have experienced a laboratory abnormality on twice weekly tocilizumab dosing, that has since resolved. Participants will receive tocilizumab 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 tocilizumab administration. Anticipated time on study treatment is 52 weeks.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT01734382 2012-000444-10 WA28029
Trial Identifiers

Eligibility Criteria:

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