ForPatients
by Roche

Healthy Volunteers

A Study to Evaluate the Bioequivalence of Tocilizumab Following Subcutaneous Administration Via an Autoinjector (AI 1000-G2) Versus a Pre-Filled Syringe in Healthy Volunteers

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02678988 WA30003

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

Trial Summary:

The study consists of an eligibility screening period, two study periods involving single doses of tocilizumab (TCZ) according to an open-label, randomized, two-period crossover design with an interval of 6 weeks between periods, and a 6 week follow-up period. Healthy participants will receive a single subcutaneous (SC) injection of TCZ via a pre-filled syringe-needle safety device (PFS-NSD) and a single injection via an autoinjector (AI). The total duration of the study is up to 16 weeks from screening to follow-up. After screening, eligible participants will be randomly assigned to one of the two possible treatment sequences (Sequence 1: AI-1000 G2 followed by PFS-NSD or Sequence 2: PFS-NSD followed by AI-1000 G2) and assigned to one of three injection sites (1: abdomen, 2: thigh, or 3: upper arm). All participant groups will receive a total of two TCZ administrations each.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT02678988 WA30003
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 65 Years	Accepts Healthy Volunteers