ForPatients
by Roche

Healthy Volunteers

A Study to Compare Pharmacokinetics (PK) of Etrolizumab Administered Subcutaneously by a Prefilled Syringe With Needle Safety Device (PFS-NSD) or an Auto-injector (AI)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02996019 GX29504

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 is a randomized, 2-part, 2-arm, open-label, parallel-group, multi-center study to compare the PK of etrolizumab administered subcutaneously by an AI (test device) or a PFS-NSD (reference device) in healthy participants. The study will comprise a pilot cohort (Part 1) to estimate the geometric mean ratio (GMR) and variability of the maximum observed concentration (Cmax) and area under the concentration-time curve (AUC) to confirm or determine the sample size for the pivotal cohort (Part 2). The pivotal cohort will demonstrate exposure comparability of Cmax, AUC from Hour 0 to the last measurable concentration (AUClast), and AUC from Hour 0 to extrapolated infinite time (AUC0-inf), values for a single dose of etrolizumab administered subcutaneously either by the AI or the PFS-NSD.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT02996019 GX29504
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 55 Years	Accepts Healthy Volunteers