ForPatients
by Roche

Healthy Volunteers

A Study to Evaluate Pain, Tolerability, Safety, and Usability of a Single Self-administered Etrolizumab by Auto-injector in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02629744 GX29503

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 study is a multi-center, single-arm, open-label study in healthy participants to assess the pain, tolerability, injection leakage, safety, and usability of a single self-administered subcutaneous (SC) dose of etrolizumab. Some participants will receive "needle-experience" training using a needle and syringe on Days -7 and -5, and health care professionals (HCPs) will then assess the participant's suitability to self-inject with a prefilled auto-injector (AI). The remainder of participants will be "needle naïve" and will not have previously self-injected. Eligible" needle experienced" and" needle naive" participants will attend an AI training visit at the study site on Day -3 (three days prior to etrolizumab dosing on Day 1). Following training and simulated injections by the participant the HCP will determine if the participant is suitable to proceed to actual etrolizumab dosing. All eligible study participants will self administer a single dose of etrolizumab (by AI) on Day 1 and will be followed up to Day 85 following dosing. Pain, tolerability, safety and usuability will be assessed.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT02629744 GX29503
Trial Identifiers

Eligibility Criteria:

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