ForPatients
by Roche

Healthy Volunteers

A Study to Assess the Tolerability and Safety of Subcutaneously (SC) Administered Immunoglobulin G (IgG) With Varying Injection Conditions

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07025577 GP45580

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase 1, Open-Label, Fixed-Sequence, Randomized Study to Assess the Tolerability and Safety of Subcutaneously Administered Immunoglobulin G With Varying Injection Conditions

Trial Summary:

This study will evaluate the safety and tolerability of SC administration of IgG in healthy participants.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07025577 GP45580
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 65 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Body mass index (BMI) 18 to 36 kilograms per meter square (kg/m^2), inclusive
- For females of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use adequate contraception during IgG administration and for 28 days after completion of IgG administration
- For males: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 28 days after the last study drug administration
- Positive human immunodeficiency virus (HIV) test
- Positive hepatitis B surface antigen or hepatitis B core antibody test
- Positive hepatitis C virus antibody test
- Regular alcohol consumption of >8 drinks/week for females or >12 drinks/week for males
- Poor peripheral venous access
- Major surgical procedure within 28 days prior to initiation of study treatment or anticipation of need for a major surgical procedure during the study
- Known hypersensitivity to IgG or any of its components or to products made with IgG
- History or presence of skin rash or other skin disorders
- Inability to sense pain (e.g., peripheral neuropathy) or have a history of or have been diagnosed with a chronic pain syndrome
- Infection or inflammation of the designated injection site (abdomen)