ForPatients
by Roche

Healthy Male Subjects

A Study to Assess the Bioequivalence of Trastuzumab Via Different Subcutaneous Delivery Platforms in Healthy Male Participants

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07214766 GP44770

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, Randomized, Two-Part, Parallel-Group Study to Assess the Bioequivalence of Subcutaneously Administered Trastuzumab Via Different Subcutaneous Delivery Platforms in Healthy Male Subjects

Trial Summary:

This two-part study will evaluate the bioequivalence, safety, and tolerability of a single SC dose of trastuzumab administered via handheld syringe/syringe pump (HHS/SP) with infusion set (IS) and an on-body delivery system (OBDS).

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT07214766 GP44770
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years & # 50 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Within body mass index (BMI) range 18 to 38 kilogram per meter square (kg/m2), inclusive. Body weight <=100 kg
- Left ventricular ejection fraction (LVEF) >= 55 percent (%) measured by echocardiogram (ECHO)
- Negative test result for drugs of abuse
- Negative test result for hepatitis B surface antigen, hepatitis C virus (HCV), or human immunodeficiency virus (HIV) antibody screen
- Negative test for latent Tuberculosis (TB) infection by QuantiFERON® TB Gold

- Agree to use contraception and will refrain from sperm donation

Exclusion Criteria:

- Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, respiratory, gastrointestinal, immunological, neurological, or psychiatric disorder; acute infection; or other unstable medical disease
- History of moderate or severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric, human, or humanized antibodies or fusion proteins
- Known sensitivity to recombinant hyaluronidase or other form of hyaluronidase
- History or presence of atrial fibrillation
- History of any clinically significant or clinically relevant cardiac condition
- History or presence of clinically significant electrocardiogram (ECG) abnormalities
- History of uncontrolled hypertension, hyperlipidemia, thyroid disorder, or diabetes
- Family history of clinically significant and clinically relevant hypersensitivity, allergy, or severe cardiac diseases
- History of previous anti-cancer treatments including pertuzumab, trastuzumab, anthracyclines, or any cardiotoxic drugs
- History of active or latent TB, regardless of treatment history
- Poor peripheral venous access
- History or presence of any malignancy, with the exception of completely excised basal cell or squamous cell carcinoma of the skin