

Healthy Male Subjects

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

Trial Status Recruiting	Trial Runs In 1 Country	Trial Identifier NCT07214766 GP44770
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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. Sponsor	Phase 1 Phase
NCT07214766 GP44770 Trial Identifiers	

Eligibility Criteria:

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

ForPatients

by Roche

- 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