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

NCT07214766

Status	RECRUITING
Phase	Phase 1
Sponsor	Genentech, Inc.
Enrollment	312 participants

Key Eligibility Criteria

Inclusion (6)

- 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

... and 1 more (see full listing online)

Exclusion (12)

- 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

... and 7 more (see full listing online)

Locations (4 total)

Anaheim Clinical Trials, Anaheim, California, United States
Daytona Beach Clinical Rsch Unit, Daytona Beach, Florida, United States
QPS Bio-Kinetic, Springfield, Missouri, United States
... and 1 more locations

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