ForPatients
by Roche

Healthy Male Subjects

A Study to Evaluate Single Subcutaneous Doses of NXT007 Among Injection Sites Abdomen, Upper Arm, and Thigh in Healthy Male Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06189508 BP45057

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:

An Open-Label, Parallel-Group Phase I Study to Evaluate the Relative and Absolute Bioavailability of Single Subcutaneous Doses of NXT007 Among Injection Sites Abdomen, Upper Arm, and Thigh in Healthy Male Participants

Trial Summary:

This is a Phase I, open-label, non-randomized, parallel-group, single-dose study in healthy adult male participants. The aim is to investigate the relative bioavailability (rBA) of NXT007 among subcutaneous (SC) injection sites (abdomen, upper arm, and thigh) and the absolute bioavailability (aBA) of SC NXT007 administration. In addition, the pharmacodynamic, safety, tolerability, and immunogenicity of a single dose of NXT007 following SC or intravenous (IV) administration are assessed.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT06189508 BP45057
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years & # 45 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Overtly healthy as determined by medical evaluation that includes medical history, physical examination, vital signs, laboratory tests, and 12-lead ECG
- Body mass index (BMI) within the range of 18.5 to 30.0 kg/m^2
- Agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agree to refrain from donating sperm

Exclusion Criteria:

- History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological, immunological, or neurological disorders capable of significantly altering the absorption, metabolism, or elimination of drugs; constituting a risk when taking the study treatment; or interfering with the interpretation of data
- History of allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies; or known hypersensitivity to any constituent of the product
- Clinically relevant medical history and/or family history or signs of thromboembolic disease such as deep vein thrombosis
- FVIII activity #120 International Units per decilitre (IU/dL) at screening
- Clinically significant abnormality on electrocardiogram (ECG) at screening such as QTcF after 10-minute supine rest >450 milliseconds (ms); marked resting bradycardia (mean heart rate <40 beats per minute [bpm]); marked resting tachycardia (mean heart rate >100 bpm); or any other clinically significant ECG abnormality
- Supine systolic blood pressure at screening #140 millimetres of mercury (mm Hg) or <90 mm Hg or supine diastolic blood pressure at screening #90 mm Hg or <40 mm Hg
- Clinically significant abnormality on protein C activity (chromogenic assay), activated protein C resistance test, protein S free antigen, and/or antithrombin III activity levels
- Poor peripheral venous access
- Any other reason that, in the judgment of the investigator, would render the participants unsuitable for study participation