ForPatients
by Roche

Hemophilia A

A Clinical Study to Evaluate the Effects of NXT007 Compared to Factor VIII Prophylaxis in Participants With Hemophilia A

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07416526 2025-522434-32-00 WO45886

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 Multicenter, Randomized, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of NXT007 Prophylaxis Versus Factor VIII Prophylaxis in People With Hemophilia A Without Inhibitors

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of NXT007 prophylaxis compared with Factor VIII (FVIII) prophylaxis in participants with severe or moderate congenital hemophilia A without inhibitors.
The study will include people aged #12 years old with severe or moderate congenital hemophilia A without inhibitors on previous FVIII prophylaxis treatment.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#12 Years	No

Inclusion Criteria:

- Diagnosis of severe (FVIII:C <1 IU/dL [International Unit per decilitre]) or moderate (FVIII:C between #1 IU/dL and #5 IU/dL) congenital hemophilia A without inhibitors against FVIII

- No documented inhibitor (i.e., <0.6 BU/mL [Bethesda unit per millilitre]), FVIII half-life #6 hours, or FVIII recovery >66% in the last 3 years prior to screening
- Documented historical negative test for FVIII inhibitor (i.e., <0.6 BU/mL) within 12 months prior to enrollment
- Documentation of the details of prophylactic and episodic FVIII treatment and of the number and type of bleeding episodes for at least the last 6 months prior to screening
- Agreement to adhere to the contraception requirements (for potential participants with childbearing potential)

Exclusion Criteria:

- Sensitivity to any of the study investigations, or components thereof, or drug or other allergy that, in the opinion of the investigator, contraindicates participation in the study
- Use of systemic immunomodulators (e.g., interferon or rituximab) at the time of enrollment or planned use during the study, except for anti-retroviral therapy to treat HIV
- Planned surgery (excluding minor procedures such as non-molar tooth extraction, incision and drainage) during the study
- History or presence of an abnormal ECG that is deemed clinically significant, (e.g., complete left bundle branch block, second- or third- degree atrioventricular heart block) or ECG evidence or clinical history of prior myocardial infarction
- Refusal to accept plasma-derived and/or blood product transfusion support in an emergency scenario
- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias such as structural heart disease (e.g., severe left ventricular systolic dysfunction, left ventricular hypertrophy), coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing)