ForPatients
by Roche

Hemophilia A

A Clinical Study to Evaluate the Effects of NXT007 Compared to Emicizumab Prophylaxis in People With Hemophilia A

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07416604 2025-522435-33-00 BO45887

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 Emicizumab Prophylaxis in People With Hemophilia A

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of NXT007 prophylaxis compared with emicizumab prophylaxis in people age 12 years and older with severe or moderate congenital hemophilia A without factor VIII (FVIII) inhibitors or with hemophilia A of any severity (severe, moderate, and mild) with FVIII inhibitors.

Hoffmann-La Roche
Sponsor

Phase 3
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 International Unit per decilitre [IU/dL]) or moderate (FVIII:C between #1 IU/dL and #5 IU/dL) congenital hemophilia A with or without inhibitors against FVIII

- Diagnosis of mild (FVIII:C between >5 IU/dL and <40 IU/dL) congenital hemophilia A with chronic FVIII inhibitors, defined as documented FVIII inhibitor (#0.6 BU/mL or #1.0 BU/mL only for laboratories with a historical sensitivity cutoff for inhibitor detection of 1.0 BU/mL) and chronic reduction of endogenous baseline FVIII:C to <5 IU/dL for #12 months
- Documented historical FVIII inhibitor assay results within the 12 months prior to enrollment
- Documentation of the details of prophylactic and episodic FVIII treatment, bypassing agent (BPA) treatment, emicizumab prophylaxis treatment, and the number and type of bleeding episodes for at least the last 6 months prior to screening
- For potential participants taking on-demand treatments prior to study entry: agreement to move to a prophylaxis treatment with either emicizumab or NXT007, according to assigned randomization

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 antiretroviral therapy to treat HIV
- Refusal to accept plasma-derived and/or blood product transfusion support in an emergency scenario
- Planned surgery (excluding minor procedures, such as non-molar tooth extraction or incision and drainage) during the study
- 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)
- 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 evidence or clinical history of prior myocardial infarction