

ForPatients

by Roche

Hemophilia A

Efficacy, Safety, and Pharmacokinetic Study of Prophylactic Emicizumab Versus No Prophylaxis in Hemophilia A Participants (HAVEN5)

Efficacy, Safety, and Pharmacokinetic Study of Prophylactic Emicizumab Versus No Prophylaxis in Hemophilia A Participants

Trial Status

Active, not recruiting

Trial Runs In

3 Countries

Trial Identifier

NCT03315455 HAVEN5 YO39309

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

Trial Summary:

This multicenter, open-label, Phase 3 study with randomized and non-randomized arms is designed to investigate the efficacy, safety, and pharmacokinetics of emicizumab in participants with hemophilia A regardless of factor VIII (FVIII) inhibitor status. Participants greater than or equal to (#)12 years old who received episodic therapy with FVIII or bypassing agents prior to study entry and experienced at least 5 bleeds over the prior 24 weeks will be randomized in a 2:2:1 ratio to the following regimens: Arm A: Emicizumab prophylaxis at 3 milligrams per kilogram (mg/kg) once every week (QW) subcutaneously (SC) for 4 weeks, followed by 1.5 mg/kg QW SC; Arm B: Emicizumab prophylaxis at 3 mg/kg QW SC for 4 weeks, followed by 6 mg/kg once every 4 weeks (Q4W) SC; and Arm C: No prophylaxis (control arm). In addition, pediatric participants less than (<)12 years old with hemophilia A and FVIII inhibitors who received episodic therapy with bypassing agents prior to study entry will be enrolled to Arm D: Emicizumab prophylaxis at 3 mg/kg QW SC for 4 weeks, followed by 1.5 mg/kg QW SC.

Hoffmann-La Roche

Sponsor

Phase 3

Phase

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Trial Identifiers

Eligibility Criteria:

Gender

All

Age

All

Healthy Volunteers

No