

Efanesoctocog Alfa Prophylaxis in Patients With Hemophilia A With Synovial Hypertrophy

NCT06941870

Status	RECRUITING
Phase	Phase 4
Sponsor	Sanofi
Enrollment	35 participants

Key Eligibility Criteria

Inclusion (8)

- Participant is more than or equal to (e)12 years old at the time of consent/assent.
- Participant has existing synovial hypertrophy, defined as at least 1 eligible* joint by the HEAD-US score (Synovitis score: 1 or 2) at the time of consent/assent.
- Participant has at least 1 eligible* joint without planned future major orthopedic procedures (example, arthroscopic synovectomy, radioisotopic or chemical synoviorthesis), or major orthopedic procedures in the past 3 months prior to the screening visit (Visit 1).
- *An eligible joint is a joint with existing synovial hypertrophy, as defined by a HEAD-US synovitis score of 1 or 2, considering hypertrophic synovium as an indication of the presence of synovitis Participant has received prophylactic treatment with hemophilia prophylaxis prescriptions in the last 12 months prior to the baseline visit (Visit 2).
- Participant is capable of understanding the written Informed Consent Form (ICF)/assent form, provides a signed and witnessed written ICF/assent form, and agrees to comply with the protocol requirements.

... and 3 more (see full listing online)

Exclusion (6)

- Has other associated clotting disorders at the time of consent/assent. Is already under efanesoctocog alfa treatment. Has a current diagnosis of an factor VIII (FVIII) inhibitor, defined as inhibitor titer e0.60 BU/mL.
- Has ITI within the last 2 years prior to the baseline visit (Visit 2). Has been enrolled in a concurrent clinical interventional study or exposed to other investigational drug(s) within 3 months prior to screening for this study.
- Is currently in an institution because of regulatory or legal order (that is, is a prisoner or a patient who is legally institutionalized).
- Is not suitable for participation, whatever the reason, as judged by the investigator, including medical or clinical conditions, or patients potentially at risk of noncompliance to study procedures.
- Is an employee or family member of the investigator or site personnel. Is involved in a specific situation during study implementation or the course of the study that may raise ethics considerations.

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

Locations (13 total)

Orthopedic Institute for Children- Site Number : 8400009, Los Angeles, California, United States

Innovative Hematology, Inc.- Site Number : 8400006, Indianapolis, Indiana, United States

University of Iowa- Site Number : 8400004, Iowa City, Iowa, United States

... and 10 more locations

<https://clinicaltrials.gov/study/NCT06941870>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).