Long-term Study Evaluating Joint Health in People With Haemophilia A Receiving Real-world Prophylactic Treatment With Efanesoctocog Alfa

NCT06940830

Status	RECRUITING
Phase	Phase 4
Sponsor	Swedish Orphan Biovitrum
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (8)

- Male or female patient with a diagnosis of haemophilia A.
- Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.
- Prescribed with efanesoctocog alfa prophylactic treatment within 6 months prior to study enrolment or at the latest at the enrolment visit, in accordance with local regulations.
- Must have received prophylactic treatment(s) with any haemophilia product(s) for at least 12 months prior to being prescribed with efanesoctocog alfa treatment.
- Have documented pre-study treatment data on haemophilia prophylaxis prescriptions and on treated bleeding episodes from the 12-months prior to being prescribed efanesoctocog alfa treatment and until enrolment into this study.

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

Exclusion (4)

- Acquired haemophilia A and other blood clotting disorders than hereditary haemophilia A.
- Any positive FVIII inhibitor result (defined as inhibitor titre e0.6 Bethesda unit \[BU\]/mL) from the medical records in connection to the switch to efanesoctocog alfa until the enrolment visit.
- Enrolment in a concurrent clinical interventional study, or intake of an investigational medicinal product (IMP), including for haemophilia prophylaxis, within 3 months prior to enrolment in this study.
- Patient not suitable for participation, whatever the reason, as judged by the Investigator, e.g., patient is not able or willing to perform the study assessments.

Locations (27 total)

Sobi Investigational Site, Zagreb, Croatia
Sobi Investigational Site, Brno, Czechia
Sobi Investigational Site, Ostrava, Czechia
... and 24 more locations