

# A Clinical Study to Assess Sutacimig in Participants With Congenital Factor VII Deficiency

NCT07347249

---

Status	RECRUITING
Phase	Phase 2
Sponsor	Hemab ApS
Enrollment	18 participants

## Key Eligibility Criteria

---

### Inclusion (4)

- Age 18 to 60 years, inclusive, at the time of signing informed consent.
- Diagnosis of FVIID defined by Factor VII:C activity  $\leq 10\%$  documented on e 2 different laboratory measurements by local laboratory assessment.
- Severe bleeding history characterized by history of a major bleeding event and/or receipt of recombinant activated FVII or fresh frozen plasma as treatment for bleeding or a severe clinical bleeding history as defined by the Investigator.
- Has the ability to provide informed consent to participate in the trial.

### Exclusion (7)

- Presence of known inhibitors to FVII or FVIIa
- History of clinically significant hypersensitivity associated with monoclonal antibody therapies.
- History of venous or arterial thrombosis or thromboembolic disease, with the exception of catheter-associated superficial vein thrombosis.
- Known thrombophilia risk by the following criteria: Homozygous Factor V Leiden (FVL), compound heterozygous FVL/Prothrombin gene mutation, antithrombin  $\leq 50\%$ , congenital protein C, and protein S deficiency with levels  $\leq 50\%$ .
- Clinically significant comorbidity that may interfere with study participation.

... and 2 more (see full listing online)

## Locations (1 total)

---

Royal London Hospital, London, United Kingdom