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Study to test the safety and effectiveness of sutacimig for people with a rare bleeding condition called congenital factor VII deficiency

Submission date 03/07/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/03/2026	**Overall study status** Ongoing	
Last Edited 10/04/2026	**Condition category** Genetic Diseases	

Plain English summary of protocol

Background and study aims
Congenital factor VII (FVII) deficiency is a rare bleeding disorder caused by genetic mutations that lead to low levels or poor function of FVII. When an injury occurs, FVII normally works with tissue factor to help start blood clotting. A lack of FVIIa results in less thrombin, which is necessary for proper blood clotting, leading to bleeding episodes.
Sutacimig (HMB-001) is a new subcutaneous treatment developed by Hemab. It binds to FVIIa and activated platelets to help generate thrombin, similar to recombinant activated FVII (rFVIIa). This Phase 2b study will evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of a single dose of sutacimig in participants with FVIID who have a history of bleeding.

Who can participate?
Participants with FVIID who have a history of bleeding.

What does the study involve?
Participants will be dosed at the clinic on Day 1 and will remain at the site for a minimum of 4 hours postdose for observation and to complete study assessments. Participants will return to the clinic at protocol-specified timepoints. The planned duration of study participation is approximately 3 months. This includes a Screening Period of up to 60 days, a treatment period of 1 day, and a follow-up period of 28 days. Up to 18 participants are expected to be enrolled in the study.
Another clinical study (ISRCTN66310879) using with sutacimig for the treatment of Glanzmann's Thrombasthenia is currently ongoing.

What are the possible benefits and risks of participating?
Benefits:
Not provided at time of registration
Risks:
The First-In-Human (FIH) study (IRAS ID 1006088) with sutacimig is currently ongoing. Based on available nonclinical data and emerging clinical data from the HMB-001-CL101 study, sutacimig is

well tolerated with the important potential risks of thromboembolic events and immunogenicity and the potential risk of injection site reactions. These potential risks will be monitored closely throughout this study and guidance is provided on appropriate mitigation.
The potential risks and burdens for participants in this study are as follows:
1. Side-effects from sutacimig treatment
- Immune response to sutacimig
- Allergic reactions
- Thrombocytopenia
- Blood clot formation
- Treating bleeding events
2. Procedural risks (such as from blood sample collection, drug injection)
3. Reproductive risks are currently unknown and we are not yet fully aware of the effects of the study drug on unborn babies, on pregnant or breastfeeding women, on breastfed babies, on the female reproductive organs or on sperm or semen.
The study doctor will explain these potential risks prior to the patient consenting to the study. Participants are required to consent to using a highly effective method of contraception if they are a woman who is able to become pregnant. Women who are pregnant or breastfeeding cannot participate in the study. Male participants with female partners who can have children must avoid sexual activity that could lead to pregnancy or use male condoms plus spermicide when having intercourse and avoid sperm donation during the study treatment and for 6 months after the dose of sutacimig.

Where is the study run from?
Hemab ApS (Denmark)

When is the study starting and how long is it expected to run for?
October 2025 to September 2026

Who is funding the study?
Hemab ApS (Denmark)

Who is the main contact?
clinicaltrials@hemab.com

Contact information

Type(s)
Public, Scientific

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None - Hemab Aps

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Additional identifiers

Integrated Research Application System (IRAS)
1012417

Central Portfolio Management System (CPMS)
69130

Protocol serial number
HMB-001-201

Study information

Scientific Title
A clinical study to assess the safety and efficacy of sutacimig in participants with congenital factor VII deficiency

Study objectives
Primary objectives:
To characterise the safety and tolerability profile of sutacimig following a single dose in participants with congenital FVIID.

Secondary objectives:
1. To characterise the systemic PK profile of sutacimig in participants with congenital FVIID.
2. To evaluate PD effects of sutacimig in participants with congenital FVIID.
3. To characterise anti-drug antibodies (ADAs) following sutacimig dosing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/08/2025, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8109; fulham.rec@hra.nhs.uk), ref: 25/LO/0547

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Congenital coagulation factor VII deficiency

Interventions
Arms:
1. Experimental: Participants with a FVII(a) level of < 10%
Assigned Interventions: Drug: Sutacimig: Sutacimig is a subcutaneously administered, bispecific antibody being developed as a prophylactic treatment option for congenital bleeding disorders.
2. Experimental: Participants with a FVII(a) level of ≥10%
Assigned Interventions: Drug: Sutacimig: Sutacimig is a subcutaneously administered, bispecific antibody being developed as a prophylactic treatment option for congenital bleeding disorders.

Duration of intervention and follow up is 57 days.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Sutacimig

Primary outcome(s)
Safety assessed by the incidence of treatment-emergent adverse events and changes in physical examinations, vital signs, clinical laboratory assessments, and electrocardiogram (ECG) parameters from Day 1 through Day 57

Key secondary outcome(s))
1. Pharmacokinetic Parameter: Maximum observed plasma concentration (Cmax) of sutacimig from Day 1 through Day 57
2. Pharmacokinetic Parameter: Time to reach maximum observed plasma concentration (Tmax) from Day 1 through Day 57
3. Pharmacokinetic Parameter: Area under the plasma concentration-time curve from time zero to last quantifiable concentration (AUClast) from Day 1 through Day 57
4. Pharmacokinetic Parameter: Area under the curve from time zero to extrapolated infinite time (AUCinf) from Day 1 through Day 57
5. Pharmacokinetic Parameter: Terminal elimination phase half-life (T1/2) from Day 1 through Day 57
6. Pharmacodynamic Parameter: Total Factor VII from Day 1 through Day 57
7. Pharmacodynamic Parameter: Factor VII Activity from Day 1 through Day 57
8. Pharmacodynamic Parameter: Prothrombin time (PT) Measurement from Day 1 through Day 57

9. Pharmacodynamic Parameter: Activated partial thromboplastin time (aPTT) Measurement from Day 1 through Day 57
10. Anti-drug antibody levels from Day 1 through Day 57

Completion date
25/09/2026

Eligibility

Key inclusion criteria
1. Age 18 to 60 years
2. Diagnosis of FVIID
3. Severe bleeding history
4. Ability to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of thrombosis or thromboembolic disease, or cardiovascular disease
2. Thrombophilia risk factors
3. Use of prohibited medications
4. Women who are pregnant or breastfeeding

Date of first enrolment
17/10/2025

Date of final enrolment
30/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal London Hospital
Whitechapel Road
London
England
E1 1BB

Sponsor information

Organisation
Hemab Aps

Funder(s)

Funder type
Industry

Funder Name
Hemab ApS

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication