

# Efficacy and Safety Evaluation Study of SCT800 in Previously Untreated Hemophilia A Patients.

NCT07437404

---

Status	RECRUITING
Phase	Phase 3
Sponsor	Sinocelltech Ltd.
Enrollment	36 participants

## Key Eligibility Criteria

---

### Inclusion (4)

- Male subjects with severe hemophilia A (FVIII:C  $\leq$  1% in central laboratory tests)
- previously untreated with pdFVIII/rFVIII, including marketed SCT800 (those who have previously used d5EDs of blood products such as cryoprecipitate or fresh frozen plasma are acceptable).
- FVIII inhibitor negative
- informed consent.

### Exclusion (5)

- Known allergy to recombinant coagulation factor VIII concentrate or any excipient; known allergy to bovine, rodent or hamster bovine;
- subjects with a history or family history of FVIII inhibitor formation;
- Clinical liver function test (ALT AST)  $\geq$  5 ULN or clinical kidney function test (BUN Cr)  $\geq$  2 ULN;
- Patients with other coagulation dysfunction diseases in addition to hemophilia A.
- International Normalized Ratio (INR)  $>$  1.5.

## Locations (1 total)

---

Beijing children's hospital, Beijing, Beijing Municipality, China