Evaluation of the Safety and Efficacy of Hemophilia A Gene Therapy Drugs

NCT06111638

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Shanghai Xinzhi BioMed Co., Ltd.
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (8)

- Subjects voluntarily sign informed consent form;
- Males e 18 years;
- Subjects are clinically diagnosed with severe hemophilia A;
- Have \> = 150 documented exposure days to a Factor VIII protein product
- No prior history of hypersensitivity or anaphylaxis associated with any FVIII immunoglobulin;

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

Exclusion (13)

- Being positive for hepatitis B surface antigen (HBsAg) or hepatitis B virus-DNA (HBV-DNA). Being positive for hepatitis C virus antibody (HCV-Ab) or hepatitis C virus RNA (HCV-RNA).
- Subjects with medical history of hepatitis B or C can be regarded as negative only when 2 required samplings are conducted at least 3 months apart and both test results of indicators aforementioned are negative, HIV positive patients or Syphilis seropositive patients;
- Currently on antiviral therapy for hepatitis B or C;
- Suffer from coagulation disorders other than hemophilia A;
- In addition to glucocorticoids, any other immunosuppressants are being used before selection;

... and 8 more (see full listing online)

Locations (10 total)

Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Beijing, Beijing Municipality, China
Southern Hospital, Southern Medical University, Guangzhou, Guangdong, China
Affiliated Hospital of Guizhou Medical University, Guiyang, Guizhou, China
... and 7 more locations