EFC17574: A Phase 3, single-arm, multicenter, multinational, open label, one-way crossover study to investigate the efficacy and safety of fitusiran prophylaxis in male participants aged >= 12 years with severe hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX

Status: Recruiting

Eligibility Criteria

Sex: Male
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 12 years or older - diagnosis of severe congenital hemophilia A or B - participants currently not on prophylaxis (CFC or BPA on-demand): A minimum of 4 bleeding episodes requiring BPA (inhibitor participants) or CFC (non-inhibitor participants) treatment within the last 6 months

Exclusion Criteria:

- co-existing bleeding disorders other than congenital hemophilia A or B - current participation in immune tolerance induction therapy (ITI) - prior treatment with gene therapy - acute hepatitis, ie, hepatitis A, hepatitis E, acute or chronic hepatitis B infection - additional exclusion criteria apply (study staff will review)

Conditions & Interventions

Conditions:
Blood Disorders
Keywords:
Hemophilia

More Information

Description: A study to test a medicine (fitusiran) injected under the skin for preventing bleeding episodes in male adolescent or adult participants with severe Hemophilia.
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IRB Number: STUDY00017896