

Prevention of Bleeding in Patients With Moderate and Severe Hemophilia A Playing Sports: A Comparison Between Factor VIII and Emicizumab Prophylaxis

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 years to 19 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Participant (if 18 years of age or older) or parent/LAR is willing and able to provide written informed consent; minor participant is willing and able to provide assent, if applicable based on site and local regulations
2. Males and females between 6 to $\leq$ 19 years of age at time of enrollment with moderate to severe Hemophilia A (FVIII activity $\leq$ 5%) without inhibitors are eligible for participation in this study
3. Participants must be on Emicizumab or standard FVIII prophylaxis per institutional/primary hematologist recommendations
4. Participants must be engaging in or registered to start participating in one or more sports activities with moderate to high risk of bleeding as defined by the NHF- Playing it Safe guidelines (numerical rating $\geq$ 2).
5. Participant must be willing to keep activity, bleed, and treatment logs for the duration of the study

Exclusion Criteria:

1. Participant/parent/LAR unwilling to provide informed consent/assent
2. Unwilling to log or document bleeds and treatment information as per study guidelines
3. Participants with any other bleeding disorders will be excluded
4. Patients who are pregnant, planning to become pregnant, or breastfeeding should not be enrolled in the study
5. Participants on concomitant FVIII replacement and emicizumab for sports participation

Conditions & Interventions

Interventions:

DRUG: Emicizumab, DRUG: FVIII

Conditions:

Hemophilia A

More Information

Description:

Hemophilia A (HA) is a genetic bleeding disorder resulting from a deficiency or absence of factor VIII (FVIII), which is necessary in the clotting process. This disorder occurs mostly in males and in severe cases causes frequent bleeding episodes in joints and muscles which can lead to progressive damage that affects mobility and quality of life. Prophylactic FVIII administered intravenously every other day has been the standard of care treatment for HA for the past few decades. Sports and physical activity are generally encouraged in patients with hemophilia on appropriate prophylactic treatment to increase strength, prevent or decrease obesity, accrue and maintain bone density and encourage normal socialization. To ensure safety with participation in sports in persons with hemophilia A (PWHA), timing of FVIII administration is often adjusted to maximize FVIII at the time of sports. The exact factor level that is needed to safely participate in sports and minimize bleeding risk is not yet known. Based on clinical practice, infusion of FVIII to near the lower limit of normal right before participation in sports generally works to prevent bleeding. The study is looking at how well the newly approved medication Emicizumab works compared to Factor VIII to prevent bleeding in patients with Hemophilia A who play sports. The study will enroll children and adolescents who are already on Emicizumab or Factor VIII who are currently playing sports.

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Phase:

IRB Number:

System ID: NCT05022459

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