Prophylactic Treatment with New Recombinant Factor IX Innonafactor (Russia) in Adolescent and Adult Patients with Hemophilia B

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Abstract

Background:

Group of patients with severe and mild forms of hemophilia B was treated with Innonafactor in prophylactic regime during 26±1 weeks. Results based on the evaluation of the frequency of bleedings development during the study period.

Aim:

To assess the efficiency and safety of rIX Innonafactor (QC "SINEIRUM", Russia) in prophylactic treatment of adolescent and adult previous treated patients with severe and mild forms of hemophilia B (< 20).

Methods:

15 Caucasian men aged between 12 to 31 years (avg 20.5±8.4) with mild (41.7%) and severe (58.3%) forms of hemophilia B were included to study. All patients received prophylactic treatment in dose 45±5 U2 times per week during 26 weeks. In cases of bleedings Innonafactor was used on demand. There were registered frequency and heaviness of bleedings in time of treatment.

Results:

7 patients (46.7) had 18 bleeding episodes in 72 hours after Innonafactor infusion (avg 1.2±1.7) during treatment. Most of them were traumatic, 5 spontaneous bleedings in mild and easy forms were registered only in 3 patients (20%). Before the start of treatment 9 patients (60%) had bleedings more than once per month, of them (26.7%) had bleedings more than once per week. For control the bleeding episode it was need one injection of Innonafactor in 55.8% cases, three injections in 14%. 26.2% cases didn't need plasmapheresis.

Residual activity of factor IX ±1% in 72 hours after infusion was registered in 100% patients with severe hemophilia B, IX >2% – in 80% patients with mild forms of disease.

We registered 5 AE. All of them were fluent as easy and hadn't relation with Innonafactor.

Conclusion:

For today we report our experience with new Russian recombinant factor IX Innonafactor. The prophylactic treatment was effective in all patients. During the treatment we didn't register SAE. All AE during the treatment were non-relation to Innonafactor. There were not register thrombotic complications, allergic reactions, the formation of an inhibitor to the factor IX.

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