Safety and Efficiency of New Nonacog Alfa Drug in the Treatment of Bleeding Episodes in Patients with Severe and Moderate Hemophilia B

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Abstract

The efficiency and safety of a new Russian recombinant factor IX - FIX (nonacog alpha, Innonafactor) GARINUM in prevention of bleeding episodes in patients with severe and moderate hemophilia B (n=9) were studied in a randomized, placebo-controlled, double-blind study in comparison with plasma-derived FIX - Octamine® F® (Octapharmazeutika Produktionsgesellschaft mbH, Austria). The main objective of this study was to test hemostatic equivalence and safety of nonacog alfa compared to Octamine® F® in patients with severe and moderate hemophilia B. The safety and efficiency were studied in "on-demand" treatment in 10 patients. According to randomization, patients were divided into 2 groups. Patients of the 1st group (n=6) received the nonacog alfa intravenous and patients of the 2nd group were given Octamine® F® in the 1st group (n=4) and Octamine® F® in the 2nd group (n=6) patients with severe hemophilia B (activity of FIX was less than 10%) and 1 patient with moderate factor levels of the severe variety (FIX was 15%). In the 2nd group 4 patients had severe and 1 patient moderate hemophilia B. During the follow up period (13±1 week) 4 bleeding episodes were registered in patients of the 1st group: 1 of them (3346.01±801.51 ME) was in the 2nd group (n=9) received the nonacog alfa (Innonafactor) and 67 (95.71%) episodes in the 2nd group (35722.22±34726.71 ME). The differences were statistically not significant (p=0.86; 2 tailed). The vast majority of bleedings were stopped with 1 - 2 doses of study drugs: 64 (100%) episodes in the 1st group and 57 (85.75%) episodes in the 2nd group (p=0.712). There were no differences in the average number of injections required to stop one bleeding episode 1.06±0.08 in the 1st group and 1.10±0.09 in the second group (p=0.93).

During follow up period patients of the 1st group received fewer doses of drug to stop bleeding (7.56±3.91) than patients of the 2nd group (11.56±11.2). But the differences were statistically not significant (p=0.929). It seems that nonacog alfa is effective to stop bleeding in 18 patients. There is not any side effects, infection transmission, or de novo inhibitor formation. The efficiency and safety of nonacog alfa compared to Octamine® F® in patients with severe and moderate hemophilia B, the results are comparable with the potential articles of interest.

The Pharmacokinetic Properties, Safety and Efficiency of Nonacog Alfa Drug in the Treatment of Bleeding Episodes in Patients with Severe and Moderate Hemophilia B

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