Safety and Efficacy of New Nonacog ALg Drug (Innonafactor) in Prophylactic Treatment in Patients with Severe and Moderate Hemophilia B

Takashi Suzuki et al., Surveillance Study - Factor IX (nonacog alfa) in Japanese Patients with Severe and Moderate Hemophilia B

During a controlled, randomized, open, prospective, multicenter clinical trial the efficacy and safety of a new domestically produced recombinant factor IX (FIX, nonacog alfa, CJSC "GENERIUM", Russia) were investigated in comparison with the original drug Benefix® (Pfizer, USA) in 18 patients (n=9) with severe and 9 with moderate hemophilia B. After screening and a 4-day washout period 18 patients were randomized to 4 groups according to coagulation activity: the 1st group patients in 1st received the nonacog alfa, the 2nd group 100 IU kg⁻¹ in 1st group FIX activity was 1-2,6% of normal, in the 3rd group FIX activity was 10-30% of normal and in the 4th group was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. The average number of bleedings during the analyzed period in patients of the 1st group was 0,22±0,44. In patients of the 2nd group there were 4 patients with severe and 6 patients with moderate hemophilia B. After screening and a 4-day washout period 18 patients were randomized to 4 groups according to coagulation activity: the 1st group patients in 1st received the nonacog alfa, the 2nd group 100 IU kg⁻¹ in 1st group FIX activity was 1-2,6% of normal, in the 3rd group FIX activity was 10-30% of normal and in the 4th group was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. The average number of bleedings during the analyzed period in patients of the 2nd group was 47,56 ±13,56% and the IVR of Octanine F was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. Desks were estimated in ½, 1, 2, 3, 4 and 5 months during 30-90 days (6 months). The main criterion of drug efficacy was the average number of bleedings during 6 months of prophylactic treatment. Efficacy and safety of a new domestically produced recombinant factor IX (nonacog alfa) with its pharmacodynamic and pharmacokinetic characteristics is comparable to Octanine F. Administration of nonacog alfa (Innonafactor) was safe and without side effects, infection transmission, de novo inhibitor incident. Its degree of recovery. Treatment with nonacog alfa (Innonafactor) was safe and without side effects, infection transmission, de novo inhibitor incident. Its degree of recovery.

Pharmacokinetics was evaluated by K-value (incremental recovery) and in vivo recovery (IVR). The study demonstrated that nonacog alfa (Innonafactor) with its pharmacodynamic and pharmacokinetic characteristics is comparable to Octanine F. Administration of nonacog alfa (Innonafactor) in patients with severe and moderate hemophilia B was effective in prophylaxis of bleeding in patients with severe and moderate hemophilia B. The average number of bleedings during the analyzed period in patients of the 1st group was 0,22±0,44. In patients of the 2nd group there were 4 patients with severe and 6 patients with moderate hemophilia B. After screening and a 4-day washout period 18 patients were randomized to 4 groups according to coagulation activity: the 1st group patients in 1st received the nonacog alfa, the 2nd group 100 IU kg⁻¹ in 1st group FIX activity was 1-2,6% of normal, in the 3rd group FIX activity was 10-30% of normal and in the 4th group was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. Desks were estimated in ½, 1, 2, 3, 4 and 5 months during 30-90 days (6 months). The main criterion of drug efficacy was the average number of bleedings during 6 months of prophylactic treatment. Efficacy and safety of a new domestically produced recombinant factor IX (nonacog alfa) with its pharmacodynamic and pharmacokinetic characteristics is comparable to Octanine F. Administration of nonacog alfa (Innonafactor) was safe and without side effects, infection transmission, de novo inhibitor incident. Its degree of recovery. Treatment with nonacog alfa (Innonafactor) was safe and without side effects, infection transmission, de novo inhibitor incident. Its degree of recovery.

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In patients of both groups, the average number of bleeding was within normal range (fig. 2). After screening and a 4-day washout period 18 patients were randomized to 4 groups according to coagulation activity: the 1st group patients in 1st received the nonacog alfa, the 2nd group 100 IU kg⁻¹ in 1st group FIX activity was 1-2,6% of normal, in the 3rd group FIX activity was 10-30% of normal and in the 4th group was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. The average number of bleedings during the analyzed period in patients of the 1st group was 0,22±0,44. In patients of the 2nd group there were 4 patients with severe and 6 patients with moderate hemophilia B. After screening and a 4-day washout period 18 patients were randomized to 4 groups according to coagulation activity: the 1st group patients in 1st received the nonacog alfa, the 2nd group 100 IU kg⁻¹ in 1st group FIX activity was 1-2,6% of normal, in the 3rd group FIX activity was 10-30% of normal and in the 4th group was analogous and amounted to 1,14 ±0,29 IU/DL per IU/kg. Desks were estimated in ½, 1, 2, 3, 4 and 5 months during 30-90 days (6 months). The main criterion of drug efficacy was the average number of bleedings during 6 months of prophylactic treatment. Efficacy and safety of a new domestically produced recombinant factor IX (nonacog alfa) with its pharmacodynamic and pharmacokinetic characteristics is comparable to Octanine F. Administration of nonacog alfa (Innonafactor) in patients with severe and moderate hemophilia B was effective in prophylaxis of bleeding in patients with severe and moderate hemophilia B. The average number of bleedings during the analyzed period in patients of the 1st group was 0,22±0,44.

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