This multicentre, open-label, prospective, single-arm study was designed to evaluate the efficacy, pharmacokinetics, and safety of IqYmune®, a highly purified 10% polyvalent immunoglobulin preparation for intravenous administration in patients with primary immunodeficiency" Krivan et al (2017).

Abstract:

This multicentre, open-label, prospective, single-arm study was designed to evaluate the efficacy, pharmacokinetics, and safety of IqYmune®, a highly purified 10% polyvalent immunoglobulin preparation for intravenous administration in patients with primary immunodeficiency. IqYmune® was administered to 62 patients (aged 2-61 years) with X-linked agammaglobulinemia or common variable immune deficiency at a dose from 0.22 to 0.97 g/kg every 3 to 4 weeks for 12 months with an infusion rate up to 8 mL/kg/h.

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A pharmacokinetic study was performed at steady state between the 8th and the 9th infusion. A single case of serious bacterial infection was observed, leading to an annualized rate of serious bacterial infections/patient (primary endpoint) of 0.017 (98% CI: 0.000, 0.115). Overall, 228 infections were reported, most frequently bronchitis, chronic sinusitis, nasopharyngitis and upper respiratory tract infection. The mean annualized rate of infections was 3.79/patient. A lower risk of infections was associated with an IgG trough level > 8 g/L (p = 0.01). The mean annualized durations of absence from work or school and of hospitalization due to infections were 1.01 and 0.89 days/patient, respectively. The mean serum IgG trough level before the 6th infusion was 7.73 g/L after a mean dose of IqYmune® of 0.57 g/kg. The pharmacokinetic profile of IqYmune® was consistent with that of other intravenous immunoglobulins. Overall, 15.5% of infusions were associated with an adverse event occurring within 72 h post infusion. Headache was the most common adverse event. In conclusion, IqYmune® was shown to be effective and well tolerated in patients with primary immunodeficiency.

Reference:

Krivan, G., Chernyshova, L., Kostyuchenko, L., Lange, A., Nyul, Z., Derfalvi, B., Musial, J., Bellon, A., Kappler, M., Sadoun, A. and Bernatowska, E. (2017) A Multicentre Study on the Efficacy, Safety and Pharmacokinetics of IqYmune®, a Highly Purified 10% Liquid Intravenous Immunoglobulin, in Patients with Primary Immune Deficiency. Journal of Clinical Immunology. July 15th. .

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