Control/Tracking Number: 11-A-4055-AAAAI
Activity: Abstract
Current Date/Time: 9/14/2010 7:13:59 PM

Pharmacokinetics (PK) of Human Immunoglobulin 10% Administered Subcutaneously Alone or Following Recombinant Human Hyaluronidase (rHuPH20) in Primary Immunodeficiency Disease (PIDD) Patients

Author Block: A. Rubinstein[1], R. L. Wasserman[2], I. Melamed[3], M. Stein[4], B. McCoy[5], W. Engl[5], H. Leibl[5], D. Gelmont[6], R. I. Schiff[6], W. J. Grossman[6];
[1]Albert Einstein College of Medicine and Montefiore Hospital, Bronx, NY, [2]DallasAllergyImmunology, Dallas, TX, [3]IMMUNOe, Centennial, CO, [4]Allergy Associates of the Palm Beaches, North Palm Beach, FL, [5]Baxter BioScience, Vienna, AUSTRIA, [6]Baxter BioScience, Westlake Village, CA.

Abstract:
RATIONALE: Intravenous (IV) and subcutaneous (SC) routes of immunoglobulin (IG) administration have both advantages and disadvantages. One disadvantage of IGSC therapy is decreased bioavailability compared to IGIV. rHuPH20 is a permeation enhancer that increases systemic absorption of SC infused fluids. This is an interim analysis of Phase 3 study that evaluated PK parameters of 10% IGSC, injected with or without rHuPH20, to assess whether rHuPH20 improves IGSC bioavailability in PIDD patients.
METHODS: PK parameters of IGSC were evaluated in a subset of nine patients with PIDD ≥12 years of age who received IVIG every 3-4 weeks, weekly IGSC without rHuPH20, and IGSC every 3-4 weeks with rHuPH20 (75 U/g IgG). IGSC doses were adjusted to ensure equivalent systemic IgG exposure to IV administration.
RESULTS: The median area under the curve (AUC) was 110 g*days/L for IV, 107 g*days/L for SC treatment without rHuPH20, and 103 g*days/L for SC treatment with rHuPH20. The median IGSC dose required to obtain equivalent bioavailability when administered with rHuPH20 was 107% (95% CI: 104-134%) of the IV dose, compared to 138% (95% CI: 127-146%) for IGSC without rHuPH20. The dose of IgG per 4 weeks was 488 mg/kg for IGIV, 668 mg/kg for IGSC alone, and 538 mg/kg for IGSC with rHuPH20. Median IgG trough levels of IGSC with rHuPH20 at the same 3- or 4-week interval were 1230 mg/dL versus 1290 mg/dL for IV.
CONCLUSIONS: rHuPH20 facilitated IGSC administration at the same intervals as IV, resulting in similar bioavailability at a lower dose compared to IGSC alone.

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Author Disclosure Information: **A. Rubinstein:** Albert Einstein College of Medicine and Montefiore Hospital, Chief Division Allergy and Immunology, Baxter Clinical SQ gammaglobulin, Primary Immunodeficiencies, Principle investigator. No personal

payment; Payment to Albert Einstein College of Medicine. **R.L. Wasserman:** DallasAllergyImmunology, Physician, CSLBehring, GSK, Consultant, Speaker, Baxter Healthcare, Talecris, Consultant, CSLBehring,Baxter Healthcare, Talecris, Octapharma, Nabi, GSK,Medimune,TEVA,, Principle investigator, George, Hartz & Lundeen, Expert witness, AAAAI, Board of Directors. **I. Melamed:** IMMUNOe, President, Grifols Educational Grant, Baxter Educational Grant, Grant, CSL Behring, Pfizer, Teva, Baxter, Octapharm, GSK, Novartis, MedImmune, Ception, Principle investigator. **M. Stein:** Allergy Associates of the Palm Beaches, President, CSL Behring, Speaker, CSL Behring, Baxter Healthcare Corp, Bio Product Laboratory, Biotest Pharmaceuticals Corp., Investigator. **B. McCoy:** Baxter BioScience, Employee. **W. Engl:** Baxter BioScience, Employee. **H. Leibl:** Baxter BioScience. **D. Gelmont:** Baxter BioScience, Employee. **R.I. Schiff:** Baxter BioScience. **W.J. Grossman:** Baxter BioScience, Employee.

Category (Complete): 306. Immunodeficiency
Keyword (Complete): Immunodeficiency: Primary ; Immunoglobulin: Administration ; Immunoglobulins
Presentation Preference (Complete): No Preference
Funding (Complete):

Primary Funding : Industry

If funded through university monies, grant monies or industry, please provide name of funding institution or company. : Baxter BioScience

How many years experience in the field of, allergy, asthma, and immunology do you have? : 40

Which category best applies to the primary author?: N/A

Is there a Protocol Number or Clinical Trial Number assigned to this study?: Yes

Clinical Trial Number : NCT00814320

: Yes

*****: Yes

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