

## Rapid Infusion Rates of Immune Globulin on Intravascular Hemolysis to Treat Idiopathic Thrombocytopenia Purpura (ITP)

<b>Title of the study:</b>	Randomized, Controlled, Open Study Investigating IGIV- C, 10% Given at Different Infusion Rates on Intravascular Hemolysis in Patients with Idiopathic (Immune) Thrombocytopenic Purpura (ITP)
<b>Investigator(s):</b>	Single center study, conducted by Dr. James Bussel, MD as the sole investigative center in the United States
<b>Study center(s):</b>	New York Presbyterian Hospital, Payson 695, 525 East 68 <sup>th</sup> Street, New York, NY 10021-4885
<b>Publications (references):</b>	Bussel JB, Hanna K; IGIV-C in ITP Study Group. Safety and tolerability of a novel chromatography-based intravenous immunoglobulin when administered at a high infusion rate in patients with immune thrombocytopenic purpura. Am J Hematol. 2007 Mar;82(3):192-8.
<b>Period of study:</b>	27 June 2003 (first subject's first visit) to 02 October 2003 (last subject's last visit)
<b>Clinical phase:</b>	2
<b>Methodology (design of study):</b>	<p>This was a prospective, randomized, single-center, and open, cross-over trial in patients with Idiopathic Thrombocytopenic Purpura (ITP). Patients must have had a confirmed diagnosis of ITP. ITP was defined as isolated thrombocytopenia in a patient with no other clinically apparent associated conditions or factors that are known to cause thrombocytopenia as defined by the ITP Practice Guidelines Committee of the American Society of Hematology.</p> <p>IGIV-C at a dose of 1.0 g/kg was given on 2 occasions as a single daily infusion for platelet counts &lt; 30 Giga/L or if clinically indicated, at maximum intervals of six weeks. Eligible patients were randomized into one of two cross-over groups. Patients randomized to Group 1 received their first IGIV-C infusion at a rate of 0.08 mL/kg/min and their second infusion at a rate of 0.14 mL/kg/min. Conversely patients randomized to Group 2 received their first IGIV-C infusion at a rate of 0.14 mL/kg/min and their second infusion at a rate of 0.08 mL/kg/min.</p>
<b>Number of patients:</b>	<p>Eight patients were enrolled and randomized. These patients ranged in age from 26 to 65 years (mean age was 47.6 years). There was 1 man and 7 women randomized.</p> <p>All subjects were valid for safety analysis.</p>

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<b>Test product, dose and mode of administration:</b>	<p>Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified (IGIV-C).</p> <p>All patients received the maximal target rates of 0.08 and 0.14 mL/kg/min IGIV-C (if tolerated) on two separate occasions, but infusions of IGIV-C commenced at an initial rate of 0.02 mL/kg/min with the rates increased to these target rates according to the following stepwise scheme.</p> <p><b>TARGET INFUSION RATE = 0.08 mL/kg/min</b></p> <p>Step 1: First 15 minutes rate = 0.02 mL/kg/min (if tolerated go to step 2)</p> <p>Step 2: Increase the rate to 0.04 mL/kg/min and run at this rate for 15 minutes (if tolerated go to step 3)</p> <p>Step 3: Increase the rate to 0.08 mL/kg/min and run at this rate until the infusion is complete</p> <p><b>TARGET INFUSION RATE = 0.14 mL/kg/min</b></p> <p>Step 1: First 15 minutes rate = 0.02 mL/kg/min (if tolerated go to step 2)</p> <p>Step 2: Increase the rate to 0.04 mL/kg/min and run at this rate for 15 minutes (if tolerated go to step 3)</p> <p>Step 3: Increase the rate to 0.08 mL/kg/min and run at this rate for 15 minutes (if tolerated go to step 4)</p> <p>Step 4: Increase the rate to 0.14 mL/kg/min and run at this rate until the infusion is complete</p> <p>Note: if an infusion related adverse event was experienced, the infusion rate should have been altered.</p>
<b>Criteria of evaluation:</b>	<p>Efficacy variables: Not applicable</p> <p>Safety variables:</p> <ul style="list-style-type: none"> <li>- Number and character of clinical (including vital signs) and laboratory abnormalities or adverse events occurring during treatment with IGIV-C when administered at a rate of 0.08 mL/kg/min versus a rate of 0.14 mL/kg/min.</li> </ul>
<b>Statistical methods:</b>	<p>All safety data, incidence and severity of all adverse events during and post infusion, vital signs during the course of each infusion, and laboratory data are summarized for each of the two different infusion rates.</p>
<b>Summary of efficacy:</b>	<p>Not applicable</p>

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**Summary of safety:** All 8 subjects were evaluated for safety. All subjects received both study drug infusions except for 1 individual whose platelet level did not decrease and hence warrant another infusion. No patient prematurely discontinued the study due to an adverse event; there were no deaths or serious adverse events and most events were mild in severity (no severe events occurred). All infusions were administered at the required target speed with no requirement for interruptions or temporary reduction in infusion speed. The rates of infusion were ramped up according to protocol, or in some cases for the rapid infusion, the rates were ramped faster than described in the protocol. The infusion related adverse events were 'headache' and 'urticaria', and occurred with a similar frequency between the two rates of infusion.

The analysis of laboratory abnormalities did not reveal any clinically important findings to distinguish the standard or slow rate from the rapid rate of infusion.