

Multicenter, Multi-country Study Underway

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Typical of most studies, the name of the most recently announced study related to post-polio syndrome is long but exactly descriptive: A Multicenter, Prospective, Randomized, Placebo-controlled, Double-blind, Parallel-Group Clinical Trial to Assess the Efficacy and Safety of Immune Globulin Intravenous (Human) Flebogamma® 5% DIF in Patients with Post-Polio Syndrome.

The main purpose of the study is to select a dose of Flebogamma® 5% DIF and confirm the efficacy of the selected Flebogamma® 5% DIF dose by assessing physical performance, as measured by 2 Minutes Walk Distance (2MWD) test.

Breaking it down, the study uses the March of Dimes clinical criteria for the diagnosis of post-polio syndrome. Other criteria to be included in the study are walking unassisted or using a cane and/or other assistive devices or orthotics (braces), age range of 18-75, BMI less than 35 kg/m², negative test for pregnancy and meet the requirements about newly weakened muscle groups.

The list of exclusion criteria is long and related to other conditions a person may have, other treatments, allergies, intolerances and more.

Participants will be randomized into groups receiving either 2g/kg Flebogamma® 5% DIF or 1g/kg Flebogamma® 5% DIF or placebo (normal saline solution) every four weeks over two days for 52 weeks. Flebogamma® 5% DIF is the trade name for Immune Globulin Intravenous (Human) manufactured by Grifols Biologicals, Inc. (Instituto Grifols, SA) headquartered in Barcelona, Spain.

Centers in the following cities are involved in the study. USA: Los Angeles, St. Louis, Syracuse, Philadelphia; Canada: Toronto, Montreal; Denmark: Aarhus, Copenhagen; Germany: Berlin, Hannover, Jena, Münster; Italy: Verona; Netherlands: Amsterdam; Poland: Lublin, Poznan, Warsaw; Romania: Bucharest; Spain: Barcelona; Sweden: Göteborg, Lund, Orebro, Stockholm.

Principal investigator Dr. Marinos Dalakas, Professor of Neurology at Thomas Jefferson University Hospital, Philadelphia, states: “This is the most promising study ever conducted in PPS because it uses a multi-potent drug that works in many different ways to safely modify the immune system, as has been successfully applied in many different autoimmune neuromuscular diseases. Even though PPS is not technically an immune disease, a number of immune factors seem to play a role. Further, this is the only study ever conducted in PPS that examines the long-term effect of such a drug.”

Dr. Kristian Borg, Professor and Chair, Division of Rehabilitation Medicine, Karolinska Institute, Stockholm, adds, “We have conducted several studies on IVIg treatment in PPS and we have recently been able to characterize subgroups of responders to the drug. It will be of great interest to be able to verify our findings in a broader multinational and multicenter study.”

Eleven of the 23 centers are currently recruiting participants. To learn more about the study, the specific centers and principal investigators in each city, visit <https://clinicaltrials.gov/ct2/show/study/NCT02176863#contacts>. Members of PHI who do not have internet access may call the PHI office (314-534-0475) to learn how to participate.

The study is approved by the United States Food and Drug Administration and Health Canada. ■

Select articles about use of intravenous immunoglobulin (IVIg) in polio survivors in chronological order.

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Effect of Intravenous Immunoglobulin in Patients with Post-Polio Syndrome – An Uncontrolled Pilot Study, Kaponides, G., Gonzalez, H., Olsson, T., Borg, K., *Journal of Rehabilitation Medicine*, 2006: 38(2): 138-140.

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IVIg in other autoimmune neurological disorders: current status and future prospects, Dalakas, M., *Journal of Neurology*, Jul 2008: 255(Supple 3): 12-6.

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IVIg treatment in post-polio patients: evaluation of responders, Ostlund, G., Broman, L., Werhagen, L., Borg, K., *Journal of Neurology*, May 2012.

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