

Journal of Child and Adolescent Psychopharmacology Manuscript Central:
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Evaluation of Intravenous Immunoglobulin in Pediatric Acute-Onset Neuropsychiatric Syndrome

Journal:	<i>Journal of Child and Adolescent Psychopharmacology</i>
Manuscript ID	Draft
Manuscript Type:	Original Research
Date Submitted by the Author:	n/a
Complete List of Authors:	Melamed, Isaac; IMMUNOe Health and Research Centers Kobayashi, Roger; University of California Los Angeles O'Connor, Maeve; Allergy, Asthma & Immunology Relief Kobayashi, Ai; Midlands Pediatrics Schechterman, Andrew; Colorado Neurocognitive Consulting Heffron, Melinda; IMMUNOe Health and Research Centers Canterberry, Sharon; Midlands Pediatrics Miranda, Holly; IMMUNOe Health and Research Centers Rashid, Nazia; Dunwoody Consulting,
Keyword:	Other Disorders
Manuscript Keywords (Search Terms):	IVIG, PANS, PANDAS, Octagam
Abstract:	<p>Objectives: Pediatric acute-onset neuropsychiatric syndrome (PANS) is a clinical diagnosis in children who have an acute manifestation of varied neuropsychiatric symptoms, including obsessive compulsive disorder (OCD), eating disorders, tics, anxiety, irritability, and problems with attention/concentration. PANS may develop as a result of a post-infectious syndrome and may represent a new form of post-infectious autoimmunity. To test the hypothesis that PANS is related to an immune dysfunction, a multi-site, open-label study was designed to explore the efficacy of a novel IVIG treatment regimen.</p> <p>Methods: The primary endpoint was evaluation of the efficacy of IVIG [Octagam 5%] in PANS over a period of 6 months (6 infusions) based on mean changes in psychological evaluation scores using 6 different assessments including the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS), Clinical Global Impression of Severity, and the Parent-Rated PANS Scale.</p> <p>Results: The final cohort consisted of 21 subjects (7 per site) with moderate to severe PANS. The mean age was 10.86 years (range: 4-16 years). Results demonstrated statistically significant reductions in symptoms from baseline to end of treatment in all 6 assessments measured. CY-BOCS results demonstrated statistically significant reductions in obsessive compulsive symptoms ($p < 0.0001$), resulting in > 50% improvement sustained for at least 8 weeks after the final infusion</p>

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	<p>and up to 46 weeks in a subset of subjects.</p> <p>Conclusions: In PANS, which may be associated with an underlying immune dysregulation, sequential infusions of IVIG [Octagam 5%] successfully ameliorated psychological symptoms and dysfunction, with sustained benefits for at least 8 weeks, and up to 46 weeks in a subset of patients. In addition, baseline immune and autoimmune profiles demonstrated significant elevations in a majority of subjects, which requires further evaluation, characterization, and study to clarify the potential immune dysfunction by which PANS manifests and progresses.</p>

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Evaluation of Intravenous Immunoglobulin in Pediatric Acute-Onset Neuropsychiatric Syndrome

Isaac Melamed, MD,¹ Roger H. Kobayashi, MD,² Maeve O'Connor, MD,³ Ai Lan Kobayashi,
MD,⁴ Andrew Schechterman, PhD,⁵ Melinda Heffron,¹ Sharon Canterberry, RN,⁴ Holly
Miranda, RN,¹ Nazia Rashid, PharmD, MS⁶

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¹IMMUNOe Research Center, Centennial, Colorado.

²University of California Los Angeles School of Medicine, Los Angeles, California.

³Allergy, Asthma & Immunology Relief, Charlotte, North Carolina.

⁴Midlands Pediatrics, Papillion, Nebraska.

⁵Colorado Neurocognitive Consulting, Centennial, Colorado.

⁶Dunwoody Consulting, Ventura, California.

Corresponding Author:

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Nazia Rashid, PharmD, MS

Dunwoody Consulting

35 West Main Street, Suite B180

Ventura, California 93001

Phone: 805-665-7642

Fax: 805-456-4333

Email: naziarashidpharmacist@gmail.com

Funding Source: This study was supported by a research grant from Octapharma AG.

Running Head: IVIG in PANS

Abstract

Objectives: Pediatric acute-onset neuropsychiatric syndrome (PANS) is a clinical diagnosis in children who have an acute manifestation of varied neuropsychiatric symptoms, including obsessive compulsive disorder (OCD), eating disorders, tics, anxiety, irritability, and problems with attention/concentration. PANS may develop as a result of a post-infectious syndrome and may represent a new form of post-infectious autoimmunity. To test the hypothesis that PANS is related to an immune dysfunction, a multi-site, open-label study was designed to explore the efficacy of a novel IVIG treatment regimen.

Methods: The primary endpoint was evaluation of the efficacy of IVIG [Octagam 5%] in PANS over a period of 6 months (6 infusions) based on mean changes in psychological evaluation scores using 6 different assessments including the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS), Clinical Global Impression of Severity, and the Parent-Rated PANS Scale.

Results: The final cohort consisted of 21 subjects (7 per site) with moderate to severe PANS. The mean age was 10.86 years (range: 4-16 years). Results demonstrated statistically significant reductions in symptoms from baseline to end of treatment in all 6 assessments measured. CY-BOCS results demonstrated statistically significant reductions in obsessive compulsive symptoms ($p < 0.0001$), resulting in $> 50\%$ improvement sustained for at least 8 weeks after the final infusion and up to 46 weeks in a subset of subjects.

Conclusions: In PANS, which may be associated with an underlying immune dysregulation, sequential infusions of IVIG [Octagam 5%] successfully ameliorated psychological symptoms and dysfunction, with sustained benefits for at least 8 weeks, and up to 46 weeks in a subset of patients. In addition, baseline immune and autoimmune profiles demonstrated significant elevations in a majority of subjects, which requires further evaluation, characterization, and study to clarify the potential immune dysfunction by which PANS manifests and progresses.