

THIS STUDY NO LONGER RECRUITING

Name of Study: Comparative Dose Study of Investigational Agent

Location: Multiple locations across the U.S. including Phoenix, Arizona.

Phoenix location: Southwest Autism Research and Resource Center, 300 N. 18th Street, Phoenix, AZ 85006

Main Eligibility Criteria: Children with Autistic Disorder with a mental age greater than 18 months; body weight at least 20 kilograms (44 pounds); seizure-free for at least six consecutive months; may not be taking psychotropic drugs and should be in good physical health; no other psychiatric conditions

Principal Investigator: Dr. Raun Melmed

Contact Information: (877) 503-7788 or www.study4autism.com

Dear Parent,

Many parents of autistic children struggle to manage the symptoms associated with Autistic Disorder. These symptoms can include speech impairment, communication difficulties and delayed mental development.

In addition, seventy-five percent of children and adolescents with Autistic Disorder have irritability symptoms such as aggression towards others, deliberate self-injury, temper tantrums, and quickly changing moods. These behaviors can significantly impair school performance, interactions with family, as well as compliance to treatment.

Johnson & Johnson Pharmaceutical Research & Development is now conducting a study to evaluate the effectiveness, safety and tolerability of a higher and lower dose of an investigational agent in children and adolescents with autism. This agent is approved for use at the higher dose. Johnson & Johnson seeks to determine if a lower dose is also effective. A lower dose may reduce the side effects some children experience when taking this medication.

To learn more about this study, please call (877) 503-7788 or visit www.study4autism.com.

You may also visit: www.clinicaltrials.gov/ct2/show/NCT00576732?term=autism&rank=61.

Sincerely,

Study Team

IAN Ref: SR00169