

THIS STUDY NO LONGER RECRUITING

Name of Study: Efficacy of Aripiprazole vs Placebo in the Reduction of Aggressive and Aberrant Behavior in Autistic Children

Location: University of Medicine and Dentistry- Robert Wood Johnson Medical School, Department of Child and Adolescent Psychiatry, 671 Hoes Lane West Piscataway, NJ 08854

Eligibility Criteria: Ages between 5 and 17 years with an Autism Spectrum Disorder

Principal Investigator: Sherie L. Novotny, M.D

Contact Information: Annie Kutlik, Research Coordinator, (732) 235-5690

Dear Parent,

I am writing this letter to offer your child an opportunity to participate in a research study at the Department of Child and Adolescent Psychiatry, Robert Wood Johnson Medical School. The study is looking at the effects of Aripiprazole (currently FDA approved for the treatment of Schizophrenia and Bipolar I disorder), more commonly known as Abilify on the aggressive and impulsive aspects of this disorder. We are recruiting children ages 5-17 diagnosed with an Autism spectrum disorder. The study takes place over eight weeks. It involves a series of diagnostic assessments, blood work, urinalysis and ECG (electrocardiogram). Thirty children will undergo baseline diagnostic and IQ testing prior to being randomized (assigned to either the placebo or drug group by chance) into an 8-week, double-blind (neither investigator nor subjects will know whether the patient will receive drug or placebo/sugar pill), placebo-controlled treatment study with aripiprazole. The patients will be seen regularly and will be assessed for medication response on different parameters (determining factors) such as irritability, aggression and mood instability using standardized rating scales, such as the Aberrant Behavior Checklist-irritability subscale which measures behaviors such as irritability, hyperactivity, stereotypy & inappropriate speech. For their participation, medication will be provided at no cost. There is no charge to participate in the study. Transportation costs will not be provided however can be arranged if necessary. For more information about study participation, please contact Annie Kutlik, our research coordinator, at (732) 235-5690.

Thank you in advance for your time and assistance.

Sincerely,

Sherie L. Novotny, M.D

Department of Child and Adolescent Psychiatry

University of Medicine and Dentistry- Robert Wood Johnson Medical School