

THIS STUDY NO LONGER RECRUITING

Name of Study: Study Of Fluoxetine in Autism (SOFIA)

Location: The Ohio State University Nisonger Center, Columbus, OH

Eligibility Criteria: Children and Adolescents with an Autism Spectrum Disorder, ages 5 through 17 years

Principal Investigator: Dr. L. Eugene Arnold

Contact Information: Lindsay Crowl, Clinical Research Coordinator. Phone: 614-688-3848. Email: Lindsay.crowl@osumc.edu

Dear Parent,

This letter is to offer your child an opportunity to participate in a research study at The Ohio State University. The purpose is to evaluate the effect of fluoxetine orally dissolving tablets (ODT) on repetitive behaviors in children and adolescents with Autism Spectrum Disorders. The study will investigate the effect of fluoxetine on the improvement of the youngster's symptoms and the effects on daily life of the patient's family. We are enrolling children and adolescents with Autism Spectrum Disorders (autistic disorder, Asperger's, and pervasive developmental disorder not otherwise specified), ages 5 through 17 years.

This is a 14-week research study comparing the safety and effectiveness of an investigational medication and a matched placebo (a fake pill) in children and adolescents who have been diagnosed with or have symptoms of autism. There is a 50% chance of getting the placebo.

All evaluations and medications for this study are provided without charge to participants. In addition, families who participate will be reimbursed some for their time and transportation. A summary can be sent to the doctor of your choice. The risks and benefits of this study will be explained to you thoroughly before you agree to participate.

If you are interested in participating or have questions, please contact Lindsay Crowl at 614-688-3848 or Lindsay.crowl@osumc.edu for more details with no obligation.

Thank you in advance for your time and assistance. We look forward working with you in the near future.

Sincerely,

L. Eugene Arnold, M.D., M.Ed.
Professor Emeritus of Psychiatry