

THIS STUDY NO LONGER RECRUITING

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

Location: Children's Hospital of Michigan

Eligibility Criteria: Children and Adolescents with Autistic Disorder, ages 5 through 17 years

Principal Investigator: Dr. Harry Chugani

Contact Information: Jamie Katusin, phone: (313) 745-0148; email: jkatusin@med.wayne.edu

Dear Parent,

I am writing this letter to offer your child an opportunity to participate in a research study at the Children's Hospital of Michigan. The purpose of this study is to assess the effect of fluoxetine orally dissolving tablets (ODT) on repetitive behaviors in children and adolescents with Autistic Disorder. The study will also investigate the effect of fluoxetine on the improvement of symptoms and the effects on daily living of the patient's family. We are recruiting children and adolescents with Autistic Disorder, ages 5 through 17 years.

This is a 14-week research study comparing the safety and effectiveness of an investigational medication and placebo (a fake pill) in children and adolescents who have been diagnosed with or have symptoms of autism. All evaluations and medications for this study are provided without cost to participants. In addition, families who participate will be reimbursed for their time. The risks and benefits of this study will be explained to you thoroughly before you agree to participate.

There is no charge to participate in the study.

If you are interested in participating, please contact:

Jamie Katusin

Phone: (313) 745-0148

Email: jkatusin@med.wayne.edu

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

Sincerely,

Dr. Harry Chugani
Primary Investigator
Child Neurology
Children's Hospital of Michigan