



 Kennedy Krieger Institute



Individuals with Autism Spectrum Disorders (ASD) are needed for a research study

Kennedy Krieger Institute is looking for children and adults, ages 5 through 21 years, with Autism Spectrum Disorders (ASD) to participate in a research study. (*ASD includes autism, Asperger's Disorder, Pervasive Developmental Disorder-Not Otherwise Specified [PDD-NOS]).

The purpose of the project is to study whether an investigational drug (arbaclofen) is safe and effective for the treatment of social withdrawal behaviors often seen in people with ASD.

Social Withdrawal behaviors may include:

- Doing nothing but sitting and watching others
- Isolating himself/herself from other children or adults
- Being difficult to reach, contact, or get through to
- Showing fixed facial expressions or lack of emotions

Eligible participants will receive up to 3 months of treatment with the study drug, arbaclofen, or a placebo (no active study drug). During the treatment period, participants will be monitored for side effects and will meet with the study doctor at Kennedy Krieger Institute every 2 to 4 weeks (up to 7 visits). During these visits participants will receive psychological, psychiatric, cognitive, and medical testing including blood draws, urine testing, and ECG. Between office visits, participants will also receive phone calls from the study doctor (10-15 phone calls total). At the end of the study treatment period, the investigational drug arbaclofen (or placebo) will be gradually withdrawn over a 4-week period.

Participation in this study will last up to approximately 5 months; it will require up to 7 visits to the Kennedy Krieger Institute and between 10 and 15 phone calls with the study doctor. For each completed visit, participants will receive \$50 compensation for their time and travel expenses. The investigational drug and all study-related evaluations are provided at no cost to the participants.

If you are interested in learning more about this study, please contact:

Study Coordinator, at 443-923-7619 or email: ResearchTrials@kennedykrieger.org
 Walter Kaufmann MD, Principal Investigator, #NA_00047889 www.clinicaltrials.gov (#NCT01288716)

Project sponsors:

This study is sponsored by Seaside Therapeutics and is being performed at up to 30 research centers in the U.S.