National Institute of Mental Health
of the National Institutes of Health (NIH)

Patient Recruitment - Pediatric Disorders

Bipolar Disorder (Pediatric) Research Study

"2. Clinical Trial of Citalopram and Methylphenidate in Severe Mood Dysregulation"

Disease and Treatment Information

Detailed Protocol Description

This study is testing the effectiveness of methylphenidate plus citalopram vs. methylphenidate plus placebo for decreasing irritability in children with severe mood dysregulation (SMD). Children with SMD display chronic anger, sadness, or irritability, as well as hyperarousal (such as insomnia, distractibility, hyperactivity) and extreme responses to frustration (such as frequent, severe temper tantrums).

Children ages seven to 17 with SMD may be eligible to participate in this 12- to 15-week inpatient or outpatient study. This study has four phases. During Phase I participants are gradually withdrawn from all current psychotropic medications. Phase II is a one-week psychotropic medication-free period. During Phase III, which lasts two weeks, participants are treated with methylphenidate alone. Phase IV lasts for eight weeks. During this time, participants continue methylphenidate treatment and are randomly assigned to also receive either citalopram or placebo.

At the end of the study, those who received methylphenidate plus placebo will have the opportunity to receive methylphenidate plus active citalopram if clinically appropriate.

All procedures and medications associated with the research are provided at no cost to participants, and transportation expenses are reimbursed by NIMH. Schooling will be provided while on the inpatient unit or in day treatment.

To find out if you qualify or for more information, please call (301) 496-8381 or email us at irritablekids@mail.nih.gov.

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