Actively Recruiting Trials

**Sponsor:** Department of Defense  
**Principal Investigator:** Randi Hagerman  
*A Controlled Double-Blind Cross-over Trial of Ganaxolone in Children with Fragile X Syndrome (October 2012-July 2015)*  
**Coordinator:** Erika Bickel 916-703-0281, erika.bickel@ucdmc.ucdavis.edu

This study assesses the safety, tolerability, and efficacy of ganaxolone, a GABA_A agonist, for the treatment of behavioral problems including anxiety and inattention in children with fragile X syndrome. The protocol involves 8 visits in 4 months with 4 blood draws, medical history exams, neuropsychological evaluation, behavioral testing, psychophysiology evaluation, ERP and eye-tracking.  
*We are recruiting 60 males and females (ages 6-17 years) with the full mutation until February 2015.*

**Sponsor:** Otsuka  
**Principal Investigator:** Julie Schweitzer  
*A Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of Fixed-dose Once a day Oral Aripiprazole in Children and Adolescents with Tourette’s Disorder (January 2013-2014)*  
**Coordinator:** Lauren Bishop 916-703-0391, lauren.bishop@ucdmc.ucdavis.edu

This study compares the efficacy of aripiprazole with placebo in the suppression of tics in children and adolescents (7-17 years) with a diagnosis of Tourette’s Disorder. The protocol involves 10 visits in 3.5 months with 4 blood draws and urine samples, 5 ECGs, physical exams, psychological testing and behavioral questionnaires for the parent.  
*We are recruiting 6 males and females (ages 7-17 years) with Tourette’s Disorder until August 2014.*

**Sponsor:** Health Resources and Services Administration (HRS&A)  
**Principal Investigator:** Randi Hagerman  
*A Controlled Trial of Sertraline in Young Children with Fragile X Syndrome (January 2012-August 2014)*  
**Coordinator:** Tasleem Chechi 916-703-0296, tasleem.chechi@ucdmc.ucdavis.edu

This study investigates the efficacy of sertraline compared to placebo in children with fragile X syndrome. The protocol involves 3 visits over 6 months, monthly phone calls the first month, monthly phone calls in months 2-6, and a blood draw at the first and last visit. Each visit consists of a medical history exam, neuropsychological evaluation, behavioral testing, psychophysiology evaluation and eye-tracking.  
*We are recruiting 60 males and females (ages 24-58 months) with the full mutation until February 2014.*

**Sponsor:** Roche  
**Principal Investigator:** Randi Hagerman  
*A randomized, double-blind, 12-week, parallel-group, placebo-controlled, study of the efficacy and safety of RO4917523 in patients with Fragile X Syndrome (May 2012-May 2014)*  
**Coordinator:** Lindsey Partington 916-703-0471, lindsey.partington@ucdmc.ucdavis.edu

This study assesses the long term safety and efficacy of RO4917523, an mGluR5 antagonist, in treating behavioral symptoms characteristic of patients with fragile X syndrome. The protocol involves 7 visits in 3 months with 7 blood draws, 3 urine samples, 4 ECGs, physical exams, and behavioral questionnaires for the parent.  
*We are recruiting 16 males and females (ages 14-15 years) with the full mutation until November 2013.*

**Sponsor:** Roche  
**Principal Investigator:** Randi Hagerman  
*A Multi-Center, Randomized, Double-Blind, 12-Week, Parallel Group, Placebo-Controlled Proof of Concept Study to Investigate the Efficacy and Safety of RO5285119 in Individuals with Autism Spectrum Disorders (December 2013-2015)*  
**Coordinator:** Lindsey Partington 916-703-0471, lindsey.partington@ucdmc.ucdavis.edu

This study evaluates the safety and tolerability of 12-week treatment with RO5285119 in individuals with autism spectrum disorder. In addition, the efficacy of 12-week treatment with RO5285119 compared with placebo in treating social communication deficits in individuals with ASD will be assessed. The protocol involves 10 visits in 5 months with 17 blood draws, 10 urine samples, 8 ECGs, physical exams, and behavioral questionnaires for the parent.  
*We are recruiting 10 males (ages 18-45 years) with autism spectrum disorder until June 2015.*

**Sponsor:** MIND Institute  
**Principal Investigator:** Kathy Angkustsiri  
*A pilot study examining the microbital composition in children with autism and gastrointestinal symptoms after use of Bifidobacterium infantis and milk oligosaccharides (January 2013-December 2014)*  
This study aims to observe the biological effects of probiotics on gut function in children with autism and gastrointestinal symptoms. In addition, the study will describe changes in behavior, specifically repetitive behavior, irritability, social withdrawal, stereotypy and hyperactivity, in relation to changes in gastrointestinal symptoms. The protocol involves 4 visits in 4 months with 3 blood draws, 4 fecal samples, 3 urine samples, 3 physical exams, and behavioral questionnaires for the parent.  
*We are recruiting 10 males and females (ages 5-8 years) with autism and irregular bowel movements until August 2014.*
Trials closed to Recruitment

**Sponsor**: NINDS  **Principal Investigator**: Robin Hansen  
*A randomized, placebo-controlled, double-masked clinical trial of buspirone in the treatment of 2-6 year old children with autistic disorder (February 2011-September 2013)*  
**Coordinator**: Erika Bickel 916-703-0281, erika.bickel@ucdmc.ucdavis.edu  
This study assesses the safety, tolerability, and efficacy of buspirone in children with autism. The protocol involves 13 visits in 12 months with 8 blood draws, physical exams, psychological testing (including ADOS, and ADI-R), behavioral questionnaires for the parent, and a PET scan that requires long distance travel.  
*Recruitment is closed.*

**Sponsor**: Novartis  **Principal Investigator**: Randi Hagerman  
*An open-label study to evaluate the long-term safety, tolerability and efficacy of AFQ056 in adult patients with Fragile X Syndrome (October 2011-December 2015)*  
**Coordinator**: Emma Hare 916-703-0472, emma.hare@ucdmc.ucdavis.edu  
This study assesses the long term safety and efficacy of AFQ056, an mGluR5 antagonist, in treating behavioral symptoms characteristic of patients with fragile X syndrome. The protocol involves 13 visits in 24 months with 4 blood draws and urine samples, 6 ECGs, physical exams, intelligence testing, and behavioral questionnaires for the parent.  
*Recruitment is closed.*

**Sponsor**: Novartis  **Principal Investigator**: Randi Hagerman  
*An open-label study to evaluate the long-term safety, tolerability and efficacy of AFQ056 in adolescent patients with Fragile X Syndrome (December 2011-January 2015)*  
**Coordinator**: Emma Hare 916-703-0472, emma.hare@ucdmc.ucdavis.edu  
This study assesses the long term safety and efficacy of AFQ056, an mGluR5 antagonist, in treating behavioral symptoms characteristic of patients with fragile X syndrome. The protocol involves 13 visits in 24 months with 4 blood draws and urine samples, 6 ECGs, physical exams, intelligence testing, a short attention assessment, and behavioral questionnaires for the parent.  
*Recruitment is closed.*

**Sponsor**: Roche  **Principal Investigator**: Randi Hagerman  
*A Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Safety and Exploratory Efficacy and Pharmacokinetic, Study of RO4917523 in Pediatric Patients with Fragile X Syndrome (July 2013-June 2014)*  
**Coordinator**: Melina Ortigas 916-703-0325, melina.ortigas@ucdmc.ucdavis.edu  
This study evaluates the tolerability and safety of two doses of RO4917523, an mGluR5 antagonist, in pediatric patients with fragile X syndrome. The protocol involves 7 visits in 4 months with 7 blood draws (including 2 days of multiple draws), 3 urine samples, 5 ECGs, physical exams, and behavioral questionnaires for the parent.  
*Recruitment is closed.*