Mood Research

A Phase II/III Trial on Rizatriptan for Vestibular Migraines (IRB# 14-004558)

Inclusion Criteria:
Age 18 – 65
Vestibular Migraine attacks lasting at least 2 hours
Episodes must have spontaneous onset

Exclusion Criteria:
Meniere’s disease
Migraine with brainstem aura
Ischemic heart disease, Stroke or TIA
History of using Rizatriptan
History of adverse response to triptan medications

Study Coordinator: Deanna Hofschulte (5-2972)
PI: Dr. Jeffrey Staab

Glutamate Probes in Adolescent Depression (IRB 14-004662)

Inclusion Criteria: Aged 13-21 years, with depression or possible depression (can be taking meds, not taking meds, medication responder, medication non-responder).

Exclusion Criteria: Pregnancy or suspected pregnancy, history of seizures, brain tumor, prior brain surgery, metal in the head (braces okay), taking medication(s) that lower seizure threshold

Study Coordinator: Tara Johnson (5-0761)
PI: Dr. Paul Croarkin

Pediatric Mood Research

Mayo Clinic Individualized Medicine Biobank for Pediatric Bipolar Disorder—An F1 at Risk Feasibility Study of Pediatric Bipolar Disorder: Genetic Mechanism (IRB 09-008144)

Inclusion Criteria: Age 5-17 years, diagnosis of bipolar I or bipolar II disorder or drug-induced manic episode

Exclusion Criteria: Actively psychotic or suicidal as evidenced by clinical symptoms, Autism/Asperger’s syndrome, seizure disorder, brain tumor, or other CNS insult

Study Coordinator: Scott Feeder (5-1975)
PI: Dr. Mark Frye

Exclusion: Currently suicidal, unwilling to taper any antidepressant therapy, any current substance abuse (cannabis excluded)

Study Coordinator: Scott Feeder (5-1975)
PI: Dr. Mark Frye

Controlled Trial of Deep Brain Stimulation in Obsessive Compulsive Disorder (IRB 12-002730)

Inclusion Criteria: Treatment refractory OCD with severity of YBOCS score ≥30 and GAF score ≤45

Study Coordinator: Cindy Stoppel (4-5914)
PI: Dr. Mark Frye

A Pharmacokinetic/pharmacodynamic Genetic Variation Treatment Algorithm versus Treatment As Usual for Adolescent Management Of Depression (AMOD) (IRB 14-005547)

Inclusion Criteria: Aged 13-18 years, with major depression or bipolar disorder and are interested in P450 testing for medication management/guidance

Exclusion Criteria: Autism Spectrum Disorder, Anorexia Nervosa, or Schizophrenia. Serious suicidal risk, CYP & serotonin transporter genomic testing within 5 years

Study Coordinator: Tara Johnson (5-0761)
PI: Dr. Paul Croarkin

Exclusion: Currently suicidal, unwilling to taper any antidepressant therapy, any current substance abuse (cannabis excluded)

Study Coordinator: Scott Feeder (5-1975)
PI: Dr. Mark Frye

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Pharmacogenomics of Mood Stabilizer Response in Bipolar Disorder (IRB 11-006207)

**Inclusion Criteria:** Age > 18: Subjects with a dx of BPI who are currently on lithium monotherapy or are interested in trying lithium monotherapy for mood management (can be on a benzodiazepine)

**Exclusion Criteria:** Renal impairment, history of lithium toxicity that required treatment, unable to attend follow-up visits

**Study Coordinator:** Scott Feeder (5-1975)
**PI:** Dr. Mark Frye

A Pharmacokinetic/pharmacodynamic Genetic Variation Treatment Algorithm versus Treatment As Usual for Management Of Depression (13-007981)

**Inclusion Criteria:** Ages 18 to 65 years: Subjects with a dx of MDD, BPI, BPII, or schizoaffective disorder (bipolar type) who have a current episode of major depression < 2 years and are interested in P450 testing for medication management/guidance

**Exclusion Criteria:** Current substance abuse/dependence, unstable TSH, AST, ALT, CBC, creatinine or electrolyte levels, P450 testing within the last 5 years, axis I or II disorder that is primary other than depression, unable to attend follow-up visits (8-week trial)

**Study Coordinator:** Jose A. Rico Jr. (5-9352)
**PI:** Dr. Mark Frye

Acute and Maintenance Intravenous Ketamine for Treatment Resistant Major Depression with Suicidal Ideation/Attempt (IRB 13-005152)

**Inclusion Criteria:** Age 18-65 yrs., Depressive episode (Bipolar I or II) with PHQ 9 score ≥ 15, TRD, suicide risk score ≥3 on SSF II-R or score of 3 on Item 9 of PHQ-9

**Exclusion Criteria:** Diagnosis of schizophrenia, schizoaffective disorder, or active psychosis, Index episode of depression greater than 2 years, Current Rapid Cycling, Currently undergoing ECT, TMS or DBS as acute series or for maintenance.

**Study Coordinator:** Jose A. Rico Jr. (5-9352)
**PI:** Dr. Mark Frye

A Feasibility Study of the Microbiome of Depression and Treatment Response to Citalopram (IRB 14-002154)

**Inclusion Criteria:** Age 18-55 years, nonpsychotic major depressive disorder (MDD), ≥10 on PHQ-9, ≥17 on the QIDS

**Exclusion Criteria:** Patients with schizophrenia, schizoaffective disorder, or bipolar I disorder

**Study Coordinator:** Deanna Hofschulte (5-2972)
**PI:** Dr. Mark Frye

Mayo Clinic Individualized Medicine: Biobank for Bipolar Disorder (IRB 08-008794)

**Inclusion Criteria:** Age 18-80 male, female, any race/ethnicity with a diagnosis of bipolar disorder type I, II, or BP schizoaffective.

**Exclusion Criteria:** Unwilling to consent to providing bio specimens to be stored in the Biobank for an indefinite amount of time, actively psychotic or suicidal.

**Study Coordinator:** Autumn Timm (3-3876) or Marjorie Gresbrink (6-6519)
**PI:** Drs. Mark Frye & Joanna Biernacka

12-week Open Randomized Comparative Effectiveness Trial of Lamotrigine vs. Fluoxetine for Bipolar Depression: Pharmacogenomic and Biomarker Predictors of Response (IRB 13-003545)

**Inclusion Criteria:** Age 18-85 with a diagnosis of bipolar I, II, or schizoaffective bipolar, must be currently depressed, pass a urine drug screen, and willing to start a new medication for their bipolar depression

**Study Coordinator:** Jose A. Rico, Jr. (5-9352)
**PI:** Dr. Mark Frye