



Behavioral Health Center
CMC - Randolph

Clinical Management of Metabolic Problems in Schizophrenia: Switching to Aripiprazole versus Continued Treatment with Olanzapine, Quetiapine, or Risperidone

Metabolic abnormalities are associated with cardiovascular morbidity and premature mortality. All of these indicators of cardiovascular risk are more common in patients with schizophrenia than in matched controls. The most appropriate treatment strategies for patients with schizophrenia and metabolic risk factors for cardiovascular disease have not been established. The purpose of this study is to assess the possible benefits of switching to a medicine with a more advantageous metabolic effect (aripiprazole) versus continued treatment on medications with less advantageous metabolic profiles (olanzapine, quetiapine, or risperidone).

This is a 24 week trial for patients with a diagnosis of schizophrenia or schizoaffective for whom a medication change may be indicated because of an increased risk of cardiovascular disease in spite of adequate control of symptoms on their current antipsychotic medication. Patients will be randomly assigned to continue treatment with olanzapine, quetiapine, or risperidone, or to switch to treatment with aripiprazole. All patients will also receive a behavioral therapy intervention focused on diet and exercise. All treatments will be open label, but raters will be blinded to treatment assignment.

All study medications and study-related evaluations are free of charge. A \$25 compensation for time and travel is given at the completion of each study visit.

Patients will receive a thorough psychiatric evaluation by a Board-certified psychiatrist, psychological and neurological assessment by a PhD licensed psychologist and laboratory and other safety monitoring by a licensed RN and phlebotomist. Ongoing assessment and safety monitoring include: physical and neurological examination, fasting clinical labs (e.g., liver functioning, cholesterol levels, thyroid), urine drug screen and pregnancy tests, 12-lead ECG, vital signs, extensive psychiatric interview, and structured psychiatric safety assessments (e.g., AIMS, BARS). Visits are scheduled weekly for the first 6 visits and occur monthly for the remainder of the trial.

Please contact our study coordinator for more information or to schedule an assessment appointment. **KARYN RIEDAL at 704.446.7511**

Treatment of Cognitive Impairment in Schizophrenia Study with Sertindole versus Quetiapine

Cognitive deficits are a major determinant and predictor of long-term disability in schizophrenia. The growing literature on cognition in schizophrenia, its neuronal correlates and its strong association with functioning has led the National Institute of Mental Health (NIMH) to initiate a treatment development program called the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS). The purpose of this study is to evaluate the neurocognitive effects of sertindole versus quetiapine in patients with schizophrenia using the MATRICS battery.

Sertindole is an atypical antipsychotic found to be at least as effective in the treatment of schizophrenia as the first-generation haloperidol and as the second-generation antipsychotic risperidone. It has also shown beneficial effects on cognitive functioning in previous trials. Quetiapine is a widely prescribed atypical antipsychotic with a well-documented antipsychotic efficacy whose neurocognitive potential has also been explored.

Patients will be randomized to double-blind treatment of either sertindole or quetiapine in a 1:1 ratio for approximately 12 weeks. Patients should have a primary diagnosis of schizophrenia, aged between 18 and 55 years. The patient's clinical status should be such that a change in antipsychotic medication is considered due to either suboptimal effects or side effects of their current medication.

All study medications and study-related evaluations are free of charge. A \$25 compensation for time and travel is given at the completion of each study visit.

Patients will receive a thorough psychiatric evaluation by a Board-certified psychiatrist, psychological and neurological assessment by a PhD licensed psychologist and laboratory and other safety monitoring by a licensed RN and phlebotomist. Ongoing assessment and safety monitoring include: physical and neurological examination, fasting clinical labs (e.g., liver functioning, cholesterol levels, thyroid), urine drug screen and pregnancy tests, 12-lead ECG, vital signs, extensive psychiatric interview, structured psychiatric safety assessments (e.g., AIMS, BARS), and a battery of cognitive and skills tests. Visits are scheduled approximately every 7 to 14 days and study staff is available 24/7 as needed.

Please contact our study coordinator for more information or to schedule an assessment appointment. **KARYN RIEDAL at 704.446.7511**

Treatment of Cognitive Impairment in Schizophrenia Study

Cognitive deficits, including impairments in areas such as memory, attention, and executive function, are a major determinant and predictor of long-term disability in schizophrenia. The purpose of this study is to evaluate the efficacy of an investigational medication, AVE 1625, in the treatment of cognitive impairment in schizophrenia.

This is a 24 week study for patients with a diagnosis of schizophrenia who are currently being treated with olanzapine (5-30mg), risperidone (2-8 mg or IM depot preparation: Risperidal Consta 25-50 mg bimonthly) or quetiapine (150-800 mg) monotherapy. Patients will continue on their current antipsychotic treatment regimen and be randomized to an adjunct therapy of oral doses of the investigational medication AVE 1625, of either 5, 10, or 30 mg or placebo. AVE 1625 is a potent and selective cannabinoid 1 (CB1) antagonist. Evidence that CBI antagonists might be attractive for treating the cognitive deficits associated with schizophrenia comes from both human and animal data. Overall, evidence to date suggests that as a co-treatment with antipsychotic therapy, AVE1625 may improve cognitive functioning while diminishing the metabolic and motor side effects induced by antipsychotic medication.

All study medications and study-related evaluations are free of charge. A \$25 compensation for time and travel is given at the completion of each study visit.

Patients will receive a thorough psychiatric evaluation by a Board-certified psychiatrist, psychological and neurological assessment by a PhD licensed psychologist and laboratory and other safety monitoring by a licensed RN and phlebotomist. Assessment, evaluation and safety monitoring include: physical and neurological examination, fasting clinical labs (e.g., liver functioning, cholesterol levels, thyroid), urine drug screen and pregnancy tests, 12-lead ECG, vital signs, extensive psychiatric interview, structured psychiatric safety assessments (e.g., BPRS, CDSS), and a battery of cognitive and skills tests. Visits are scheduled approximately every 14 days and study staff is available 24/7 as needed.

Please contact our study coordinator for more information or to schedule an assessment appointment. **DINEEN GARDNER at 704.446.7511**

ADULT ADHD STUDY (Ages 18-30)

Research indicates that young adults with ADHD are at an increased risk for a variety of problems in daily living (e.g., auto accidents, substance abuse, relationship difficulties, and mood and anxiety issues). This study is investigating whether treating ADHD in young adults will improve functional outcomes for these types of problems.

This is a 12-week, randomized, placebo-controlled, double-blind trial with where patients are randomized to either atomoxetine (brand name Strattera) or placebo in a 1:1 ratio. All patients who complete the first part of the study, regardless of what treatment they are randomized to, are then eligible to continue with the 12-week open-label extension phase. During this phase patients will be administered open-label atomoxetine. Atomoxetine is a non-stimulant medication, already approved by the FDA for treatment of ADHD, which is not subject abuse associated with stimulant medications that are sometimes used to treat ADHD.

All study medications and study-related evaluations are free of charge. A \$25 compensation for time and travel is given at the completion of each study visit.

Patients will receive a thorough psychiatric evaluation by a Board-certified psychiatrist and psychological assessment by a PhD licensed psychologist, and laboratory and other safety monitoring by a licensed RN and phlebotomist. Assessment, evaluation and safety monitoring include: physical and neurological examination, fasting clinical labs (e.g., liver functioning, cholesterol levels, thyroid), urine drug screen and pregnancy tests, 12-lead ECG, vital signs, extensive psychiatric interview, structured psychiatric safety assessments, and a battery of functional assessment measures. Visits are scheduled approximately every 2 to 3 weeks and study staff is available 24/7 as needed.

Please contact our study coordinator for more information or to schedule an assessment appointment. **DINEEN GARDNER at 704.446.7511**

Bipolar I Disorder (Depressed) Study

This is a randomized, double-blind, placebo-controlled Phase 3 trial of patients diagnosed with bipolar I disorder, depressed. This study is an expansion of previous clinical work that found olanzapine monotherapy to be more effective than placebo in the treatment of depressive symptoms in patients with Bipolar Disorder.

Patients will be randomized to receive either olanzapine (5-20 mg/day) or placebo at a 2:1 ratio during a 6-week, double-blind treatment phase. All patients who complete the first 6 weeks of the study, regardless of the treatment they were randomized to, will be eligible to participate in an 18-week, open-label extension phase where all patients receive olanzapine.

All study medications and study-related evaluations are free of charge. A \$25 compensation for time and travel is given at the completion of each study visit.

Patients will receive a thorough psychiatric evaluation by a Board-certified psychiatrist, psychological and neurological assessment by a PhD licensed psychologist and laboratory and other safety monitoring by a licensed RN and phlebotomist. Assessment, evaluation and safety monitoring include: physical examination, clinical labs (e.g., liver functioning, cholesterol levels, thyroid), urine drug screen and pregnancy tests, 12-lead ECG, vital signs, extensive psychiatric interview, structured psychiatric safety assessments (e.g., DIEPSS, MINI), and multiple measures specifically related to symptoms of Bipolar disorder. Visits are scheduled approximately every 7 days for the first 10 visits and every 2 to 4 weeks for the remaining 5 visits. However, study staff is available 24/7 if needed.

Please contact our study coordinator for more information or to schedule an assessment appointment.

KARYN RIEDAL, RN AT 704.446.7509