Have you been diagnosed with Schizophrenia, Schizoaffective or Delusional Disorder?

We are looking for volunteers between the ages of 18-68 years old interested in participating in a weekly research study.*

Please call: (646) 754-4803

*up to $400.00 in compensation for participation.

Brief Summary

This study is a placebo-controlled 12 week trial of D-Cycloserine (DCS) augmentation of once-weekly CBT sessions in 60 schizophrenia subjects with antipsychotic-resistant delusions. In addition to testing efficacy, this trial will characterize DCS effects in terms of time course and persistence of response and will examine DCS effects on memory consolidation and cognitive flexibility as possible mediators of DCS enhancement of CBT for delusions.

Detailed Description

This study consists of a placebo-controlled 12 week trial of DCS augmentation of once-weekly CBT sessions in 60 schizophrenia subjects with antipsychotic-resistant delusions. In addition to testing efficacy, this trial will characterize DCS effects in terms of time course and persistence of response and will examine DCS effects on memory consolidation and cognitive flexibility as possible mediators of DCS enhancement of CBT for delusions. This study will be conducted by the Schizophrenia Research Group of the NYU Langone Medical Center at One Park Avenue 8th Floor and the Psychiatry Outpatient Clinic of Bellevue Hospital located in New York, NY.

Upon signing consent, patients will undergo screening procedures to assess eligibility. A diagnosis of schizophrenia or schizophreniform disorder will be determined by the Structured Clinical Interview for DSM IV (SCID) completed by a research clinician using all available clinical data and will be confirmed by consensus diagnosis. A comprehensive medical history and physical exam, including measurement of vital signs, will be performed. A psychiatric history, including diagnosis, treatment history, current medications, and substance use will also be performed. A research assistant will complete the demographics and administer the Scale for Assessment of Positive Symptoms-Delusions (SAPS-D).

At screening only, a fasting blood sample will be obtained to perform routine laboratory tests including electrolytes, BUN, creatinine, liver function tests, fasting glucose, calcium, phosphate, magnesium, albumin and CBC with differential. Urinalysis will be performed to identify unstable medical illness. A urine toxicology screen will be performed and a urine pregnancy test will be done for women of child bearing potential.

Subjects who meet study eligibility criteria will complete the Logical Memory Test portion of the Weschler Memory Scale-III (WMS-III) one week before the baseline visit.

The baseline visit will include the following assessments: SAPS-D, Psychotic Symptom Rating Scales (PSYRATS), Brief Psychiatric Rating Scale (BPRS), Scale for the Assessment of Negative Symptoms (SANS), Calgary Depression Rating Scale (CDRS), Clinical Global Impression (CGI), Heinrich's Quality of Life Scale (Heinrich's QOL). At the baseline visit the following cognitive assessments will be administered: the Logical Memory Test of the WMS-III, The Wisconsin Card Sort Test (WCST), Verbal Fluency Test (VFT), and the MATRICS Consensus Cognitive Battery (MCCB).

The clinical battery of assessments including the PSYRATS, BPRS, SANS, CDRS, CGI, and Heinrich's QOL will be performed on weeks 4, 8, 12, 24, and 36. The delusions section only of the PSYRATS will be performed on weeks 2, 3, 6, and 10. The Logical Memory Test will be administered on screening visit 2, baseline, and week 3. The Alternative Beliefs Exercise will occur on weeks 3, 4, and 12. The WCST and VFT will be given to participants at the baseline visit and week 12. Side effects will be assessed using the Systematic Assessment for Treatment Emergent Events (SAFTEE)on weeks 3, 4, 8, and 12.

Beginning at week 1, participants will engage in hour long sessions of Cognitive Behavioral Therapy for delusions. This treatment course will continue weekly from week 1 until week 12 (12 sessions).

For the first two sessions of CBT during weeks 1 and 2, both the experimental and the placebo group will receive a 50 mg placebo pill by mouth one hour before CBT sessions. Starting week 2, the placebo and experimental groups will receive their respective drugs one hour before CBT sessions from weeks 3-12 (50 mg placebo by mouth to placebo group, 50 mg D-cycloserine by mouth to experimental group).

The primary outcome of interest in the study is the change in PSYRATS Delusions Subscale total score compared to placebo from baseline to week 12. Secondary outcome measures include changes as defined by a 20% reduction in PSYRATS Delusions Subscale total score from baseline after 2 weeks of DCS treatment versus placebo as well changes as defined by maintenance of a 20% or greater reduction in the PSYRATS Delusions Subscale total score from baseline at a 3 and 6 month follow up as compared to placebo.