Adaptive Phase II Study to Evaluate the Safety & Efficacy of NaBenÂ®

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 12 Years to 17 Years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• Male or female subjects who are between 12 and 17 years of age inclusive

• Physician confirmed DSM-IV or -V diagnosis of schizophrenia based on MINI International Neuropsychiatric Interview for Schizophrenia and Psychotic Disorders Studies for Children and Adolescents, version 6.0 (MINI-KID, Version 6.0)

• Are clinically stable with residual symptoms, defined as a total score of â‰¥ 60 of PANSS and a score of â‰¥ 40 for SANS

• An unchanged antipsychotic medication regimen for at least eight (8) weeks prior to randomization into the study and expected to remain unchanged during the study (longer for depot or long-acting antipsychotics: ten (10) months for Aripiprazole (MaintenaÂ®) and Paliperidone (XeplionÂ®); six (6) months for Olanzapine pamoate monohydrate (ZypadheraÂ®); and at least 6 times duration of the reported half life or minimum four (4) months for other depot or long-acting antipsychotics)

• In good general physical health and all physical exam, neurological exam and laboratory assessments (urine/blood routine, biochemical tests and ECG) are clinically unremarkable per the investigator

• Subject has a negative urine illicit drug screening test

• Subject understands and is willing to sign the Informed Assent Form (IAF) prior to study entry and agrees to be available for all the study visits

• The subject's guardian understands and is willing to sign the Informed Consent Form (ICF) prior to study entry and agrees to be available for all the study visits

• Must not be a danger to self or others and must have family support available to be maintained as outpatients

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Exclusion Criteria:

• Meets the DSM-IV or -V criteria at screening for mental retardation, dissociative disorder, bipolar disorder, major depressive disorder, schizoaffective disorder, schizophreniform disorder, autistic disorder, or primary substance induced psychotic disorder. Other comorbid disorders; e.g., attention-deficit hyperactivity disorder (ADHD), are allowed as long as schizophrenia is the primary diagnosis and the comorbid disorder(s) do not require medication.

• Subjects whose illness was resistant to antipsychotics according to prior trials of two different antipsychotics of adequate dose

• History of epilepsy, head trauma, or neurological illness other than Tourette's syndrome

• History of allergic reaction to sodium benzoate

• Serious medical illnesses such as acute or chronic renal disease, liver failure or heart disease that, in the opinion of the investigator, may interfere with the conduct of the study.

• Current substance abuse or positive urine illicit drug screening or history of substance dependence (including alcohol, but excluding nicotine and caffeine) in the past three (3) months.

• Use of depot antipsychotics in the past six (6) months

• Inability to follow protocol

• Body Mass Index (BMI) > 35

• Female subjects who are pregnant (as confirmed by urine pregnancy test performed at screening Visit) or are nursing, or who do not agree to abstinence or birth control during the study

• Cancer within the last three (3) years except for basal cell carcinoma and squamous cell carcinoma

• Previous participation in an intervention trial within 30 days of randomization

• Subjects whose PANSS score has decreased more than 10 percent during the Screening Phase

Conditions & Interventions

Interventions:
Drug: NaBenÂ®, Drug: Placebo
Conditions:
Schizophrenia
Keywords:
Sodium Benzoate, Schizophrenia, Adolescent, Antipsychotic, Anti-psychotic, NMDA, NaBen, pediatric

More Information

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