

Acute Schizophrenia Phase 2 Case Study

A Phase 2 Six Week, Multicenter, Randomized Double-Blind Placebo Controlled Study to Evaluate Efficacy Safety and Tolerability Of Oral XXXXX Once Daily and Aripirizole Once Daily for Treatment of Hospitalized Adult Patients with Acute Schizophrenia

St. Louis Clinical Trials

Phase: 2

Indication: Schizophrenia (Acute)

of Subjects: 10

Inpatient Period: 6 weeks

Key Elements:

- Inpatient
- Long Confinement

OBJECTIVES

Primary

Change in PANSS Total Score

Secondary

Comparison of treatment group vs. placebo

- CGI-S and CGI-I scores
- PANSS positive subscale score
- PANSS negative subscale score
- Response rate
- PSP score

Ratings

Positive and Negative Syndrome Scale (PANSS)
Clinical Global Impression-Severity (CGI-S)
Clinical Global Impression-Improvement (CGI-I)
Personal and Social Performance Scale (PSP)
Simpson-Angus Scale (SAS)
Abnormal Involuntary Movement Scale (AIMS)
Barnes Akathisia Rating Scale (BARS)
Columbia-Suicide Severity Rating Scale (C-SSRS)

Lab Assessments

Screening

Day 1: 0.5, 3, 10, and 20 hr post-dose

Week 3: 0.5, 3, 10, and 20 hr post-dose ECGs

Weekly

Standard 12-lead ECGs performed supine and at rest for ≥ 5 minutes prior to the ECG.

Vitals

Weekly

Blood pressure and heart rate measured in the supine, sitting, and standing positions after the subject has been in each position for at least 3 minutes.