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Opioid Withdrawal Case Study

A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Efficacy, Safety, and Dose-Response Study of XXXXX in the Treatment of Opioid Withdrawal (Days 1-7) Followed by Open-Label, Variable Dose XXXXX Treatment (Days 8-14)

Midwest Clinical Research Center

Phase: 3
Indication: Opioid Withdrawal
# of Subjects: 60
Inpatient Period: 7 days

Key Elements:

- Rescue Site
- High Enrollment
- Inpatient

OBJECTIVES

Primary

Investigate the efficacy, safety, and dose-response of XXXXX (2.4 mg or 3.2 mg per day) in reducing withdrawal signs and symptoms and facilitating completion of detoxification/extending treatment retention in subjects undergoing detoxification.

Secondary

Compare safety measures in the 2.4 mg and 3.2 mg total daily dose groups to assess whether the lower dose results in fewer and less severe adverse events than does the higher dose.

Assessments

Subjective Opiate Withdrawal Scale (SOWS) Clinical Opiate Withdrawal Scale (COWS)
Modified Clinical Global Impressions Scale (MCGI) Mini International Neuropsychiatric Interview (M.I.N.I.)
Columbia-Suicide Severity Rating Scale (C-SSRS)
Objective Opiate Withdrawal Scale (OOWS-Handelsman) Visual Analog Scale for Efficacy (VAS-E)

Pharmacokinetic Sampling - 32 per subject

ECGs – 17 per subject
Day -6 – 4 readings to be time-matched to the post randomization schedule
Day 1 and 7 – 4 readings per day
Day 2 and 4 – 1 reading per day
Day 8 – 2 readings
Day 14 – 1 reading

Vitals – 66 per subject