

Study: # 7501 entitled LORCASERIN IN COMBINATION WITH XR-NALTREXONE FOR RELAPSE PREVENTION
OPIOID USE DISORDER

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Data Analysis Plan created 5-25-2017

Data analysis

All participants were randomized 2:1 lorcaserin to placebo and stratified by severity of use (Low: ≤200 mg or ≤5 bags vs. High: >200 mg or > 5 bags). The randomization scheme was skewed toward the experimental group in order to maximize the amount and precision of information on the feasibility of lorcaserin treatment. All participants were block randomized with randomly selected blocks of size three, six, and nine. The randomization sequence was designed by an independent statistician and utilized by the research pharmacist. Participants and all other study staff were blind to treatment assignment.

The primary outcome is successful induction onto XR-NTX. Secondary outcomes are: (a) severity of acute withdrawal during detoxification and induction prior to the first injection, and (b) and receiving the second injection of XR-NTX.

The outcomes of successful induction onto XR-NTX and receiving 2nd injection will be analyzed in SAS® using logistic regression with predictors: treatment (lorcaserin vs. placebo), age, baseline severity of use (high vs. low), and opioid type. A 4-level categorical predictor will be created to represent opioid type (heroin vs. opioid pills) and whether subjects were fentanyl positive at baseline. The categories are: (1) fentanyl-positive heroin, (2) fentanyl-negative heroin, (3) fentanyl-unknown heroin, and (4) fentanyl-negative opioid pills (reference group).

Withdrawal during the induction period, as measured by COWS and SOWS, will be analyzed using longitudinal mixed effect models with a random intercept for participant and an autoregressive correlation structure (AR1) to account for the within subject correlation. Predictors included: treatment, time, and time-by-treatment two-way interaction, adjusted by the baseline withdrawal score, age, baseline severity of use, and opioid type.

Retention to study week 8 and time to drop out will be compared using Kaplan-Meier curves and Cox proportional hazard models.

All analyses described in the preceding sections will be conducted on the intent-to-treat sample of all randomized participants with 2-tailed tests and a significance level of 5%.