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Grant: Multicenter Trial of Combined Pharmacotherapy to Treat Cocaine Dependence
IRB# 6698

PI: Frances R. Levin M.D.[1,2]

1. New York State Psychiatric Institute, Division of Substance Abuse[1]
1051 Riverside Drive
New York, NY 10032
USA

2. Department of Psychiatry, College of Physicians and Surgeons of Columbia University[2]
630 West 168th Street
New York, NY 10032
USA

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Data Analysis

The primary outcome was a dichotomous measure of a clinically meaningful treatment response, defined as three consecutive weeks of abstinence (no cocaine use based on self-report confirmed by urine toxicology) at the end of the 12-week medication phase of the trial. Secondary outcomes were (1) dichotomous measure of at least 3 consecutive weeks of abstinence during the study, (2) dichotomous longitudinal, weekly status of cocaine use determined by urine toxicology samples per subject, positive status occurs if at least one urine sample was positive for benzoylecgonine, (3) continuous longitudinal, symptoms of cocaine withdrawal as measured by the Cocaine Selective Severity Assessment (CSSA) assessed at week 6,10, and 14, (4) continuous longitudinal, weekly cocaine cravings as measured by the Brief Substance Craving Scale (BSCS), and (5) survival, time to dropout.

The dichotomous primary and secondary outcome (1) was analyzed using either exact or conventional logistic regressions with predictor treatment (MAS-ER and topiramate vs. placebo), and covariates: site (binary, UPENN vs. CUMC) and baseline severity of cocaine use (continuous, total number of cocaine use days in the 28 days prior to randomization). Secondary outcomes (2) – (4) were analyzed using longitudinal mixed effect models with logit link function for binary outcomes and linear link functions for continuous outcomes. Times to dropout (5) were compared using Kaplan-Meier curves and log-rank statistics.

All analyses were conducted in SAS® and on the intent-to-treat sample of all randomized patients. All statistical tests were 2-tailed at a significance level of 5%, unless otherwise stated.