

Randomized Placebo-Controlled Trial of Baclofen for Cocaine Dependence: Preliminary Effects for Individuals With Chronic Patterns of Cocaine Use.

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Background: This screening trial evaluated whether the GABA_B agonist baclofen demonstrated sufficient clinical efficacy to recommend an adequately powered trial of the medication as a pharmacotherapy for cocaine dependence.

Method: Participants with cocaine dependence verified by the Structured Clinical Interview for DSM-IV were randomly assigned to baclofen (N = 35; 20 mg t.i.d.) or placebo conditions (N = 35; identical in appearance and dosage rate) using a 2-group, experimental, 16-week double-blind design featuring thrice-weekly cognitive-behavioral drug counseling groups. Outcomes were retention, cocaine use, cocaine craving, and adverse events.

Results: A generalized estimating equation (GEE) model showed that participants assigned to receive baclofen demonstrated statistically significant reductions in cocaine use over those assigned to receive placebo as indicated by urine drug screening results ($\chi^2 = 5.34$, $df = 1$, $p = .021$). Confirming the GEE model, longitudinal analyses showed that participants assigned to receive baclofen demonstrated significant and stepwise increases in the probability of providing benzoylecgonine-free urine samples throughout the trial as the number of benzoylecgonine-positive samples increased during baseline ($\chi^2 = 10.63$, $df = 1$, $p = .001$). Participants assigned to placebo demonstrated no such association. Univariate analyses of aggregates of urine drug screening showed generally favorable outcomes for baclofen, but not at statistically significant levels. There was no statistical significance observed for retention, cocaine craving, or incidence of reported adverse events by treatment condition.

Conclusions: Project findings demonstrated initial clinical efficacy of baclofen over placebo in reducing cocaine use when delivered concurrent with thrice-weekly drug abuse counseling sessions. The effects of baclofen were particularly apparent for those participants with chronic levels of cocaine use at baseline and provide support for a full-scale efficacy trial for baclofen, especially among this subgroup of patients.