Combining Varenicline and Naltrexone for Smoking Cessation and Drinking Reduction

DATA ANALYSIS PLAN

NCT02698215

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Analyses were conducted in SAS Statistical Software Version 9.4. All analyses were of the intention-to-treat type. Since all participants took the first dose of the study medication under observation during the randomization visit, all participants were included in the subsequent analyses. The dichotomous primary outcome for smoking cessation at the 26-week follow up was analyzed using a Chi-Square test comparing smoking cessation rates for the two medication conditions. For the purpose of these analyses, all individuals who dropped out from the trial were considered to have returned to smoking, per guidelines for smoking cessation trials. For the drinking outcomes, all of which were continuous, a series of multilevel models, via Proc Mixed, were conducted for each outcome separately, during the 12-week treatment period and for the entire 26-weeks of the trial, which is consistent with pharmacotherapy trials for excessive drinking. These models tested whether the two medication groups differed in alcohol use over the 12-week medication period and across the entire 26-weeks of the trial. All models for drinking outcomes controlled for baseline drinking levels.