Dextromethorphan in Fibromyalgia Statistical Analysis Plan

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Statistical Analysis Plan

Statistical analyses were performed in SAS software, Version 9.4 of the SAS System for Windows (SAS Institute Inc., Cary, NC, United States). The primary outcome was the difference in daily self-reported general pain during the last four weeks of placebo versus the last four weeks of DXM treatment. Normality testing was performed with Shapiro–Wilk tests. Participant outcome scores were meancentered by participant, allowing analyses to reflect within-person changes to the treatments, rather than between-person differences. A generalized estimating equations (GEE) model is fitted to predict daily symptom severity based on study condition (placebo, DXM), assuming the autoregressive correlation structure and normal distributions. The grouping variable was subject ID. Significance of the parameter estimates was assumed at p<0.05. There were no corrections for multiple comparisons.

The secondary outcome (self-reported physical activity) was tested using the same GEE approach. Additionally, exploratory analyses (highest pain, muscle pain, fatigue, and depressed mood) were tested in separate GEEs.