

Study name: Study to Compare the Awakening Threshold Effects of Belsomra 10 mg and 20 mg to Placebo in Non-elderly Insomniacs

ClinicalTrials.gov ID: NCT01573338

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Statistical Analysis Plan

The primary study endpoint is the AAT in db for each treatment period in a completers database. Planned comparisons using t tests will be performed to determine statistical significance between each of the two suvorexant doses and placebo for each of the study outcome measures.

Given that standards exist for sound levels of environmental danger warning (i.e., fire alarms), and to test for the robustness of the study results, sensitivity analyses will be performed using generalized linear mixed model approach with a logit link function to assess for differences in odds of sleeping through an 85-db stimulus (the equivalent of a standard fire alarm) by condition.