Study Title:
Effects of preoperative combined use of acetaminophen and ibuprofen on the control of pain following orthodontic treatment

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NCT #03523988
Statistical Analysis Plan

Data analysis was performed blinded for the medication groups. Descriptive statistics were determined for the pain scores at each time interval for the three experimental groups. A one-way analysis of variance (ANOVA) and Tukey’s post-hoc test was used to determine the differences in mean pain scores at each time interval among the three groups. Results were determined to be statistically significant at P<0.05.

A similar study[^1] found the combined mean pain scores of acetaminophen and ibuprofen to be 24.8mm±17.1 (mean±SD) and 20.1mm±13.5, respectively, when measured using a 100-mm VAS. Clinical significance was established by a difference in mean pain scores of 10mm or greater. Each group must have a sample size of 46 participants in order to demonstrate a statistical significance using the described data at α=0.05 and power=80%.