

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 study¹ found the combined mean pain scores of acetaminophen and ibuprofen to be $24.8\text{mm}\pm17.1$ (mean \pm SD) and $20.1\text{mm}\pm13.5$, 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 $\alpha=0.05$ and power=80%.

¹Bradley R, Ellis P, Thomas P, Bellis H, Ireland A, Sandy J. A randomized clinical trial comparing the efficacy of ibuprofen and paracetamol in the control of orthodontic pain. Am J Orthod Dentofacial Orthop. 2007;132:511–7.