

## **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<sup>1</sup> found the combined mean pain scores of acetaminophen and ibuprofen to be  $24.8\text{mm} \pm 17.1$  (mean  $\pm$  SD) and  $20.1\text{mm} \pm 13.5$ , 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  $\alpha = 0.05$  and power = 80%.

<sup>1</sup>Bradley 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.