Postoperative Pain Management in Rhinoplasty: A Randomized Controlled Trial

Statistical Analysis Plan
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Study power was calculated using G*Power 3.1.9.6 software based on independent samples t-test based on difference between two means. This was a non-inferiority trial to demonstrate that Acetaminophen (APAP)- Ibuprofen (IBU) is not 'inferior' to APAP-Hydrocodone (HC). In other words, the combination of APAP-IBU is 'not unacceptably worse' than the combination of APAP-HC. Thus, the null hypothesis stated that the combination of APAP-IBU is worse than the combination of APAP-HC by more than -Δ, where -Δ is the 'non-inferiority margin'. In this study, the 'non-inferiority margin' was based on the difference between treatment groups in change in pain severity based on a 0-100 pain VAS scale. The minimal clinically significant difference for pain numeric rating scale has usually been established at around two points on a zero to 10 scale (20 points for a visual analogue scale from zero to 100). The standard deviation (SD) of change in pain severity of four points resulted in effect size 'd' (Cohen's d) of 0.5. Due to non-inferiority design, a one-tailed p-value was used resulting in the following estimates: α err prob = 0.05; power (1-β err prob) = 0.80; allocation ratio N2/N1 = 1; non centrality parameter δ = 2.52; critical t =1.66; df =100; sample size per group = 51; and total sample size = 102.

Descriptive statistics were reported as mean (SD), and as absolute numbers and percentage where appropriate. Treatment groups were compared using the Pearson Chi-squared test or Fisher's exact (if n<5) for categorical variables and the t-test for continuous variables. To assess the severity of postoperative pain experienced by patients over time in both the groups, a univariate linear regression was utilized to examine differences in mean pain VAS scores at various dosage intervals, between groups. A multivariable linear regression was utilized to analyze the effect of number of inferior turbinate reduction (ITR) or osteotomies performed, number of study medications consumed, the number of additional tramadol tablets taken by the study participants, or their postoperative periorbital sequelae of eyelid edema, ecchymosis, and hemorrhage on differences in mean postoperative pain VAS scores between treatment groups. For analyses of the SCHNOS (O and C) and the VAS (F and A) scores, since all 130 patients did not have a postoperative score at both time intervals, a mean postoperative score (SD) was calculated for each treatment group and compared to their mean preoperative scores utilizing a paired t-test. The calculated mean changes in score (∆) was compared between the two treatment groups utilizing an unpaired t-test. Two-tailed *p*-values were reported, when appropriate. The level of significance of *p*-value was set at <0.05. All analyses were carried out using Stata/BE Statistical Software: Release 19 College Station (Stata Corp LP, TX, USA).