

Cover Page

Title: Comparison of Intramuscular Ketorolac at Two Single-Dose Regimens for Treatment of Acute Musculoskeletal Pain in a Military Emergency Department: A Randomized Controlled Non-Inferiority Trial

NCT: Not received yet

Date: 2/5/2021

Statistical Analysis Plan

Data analysis will be performed using the statistical software SPSS (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.). The primary outcome will be tested using an independent samples *t*-test. To assess for any differences in VAS scores based on demographic data, independent *t*-tests will be utilized. To assess for normality of distributions in the sample's continuous demographic and clinical characteristics, z-scores will be formed by dividing skewness by the standard error of skewness. This is performed to ensure that parametric measures can be used for the two groups. A Fisher's exact test will be used to assess the lower dose for a difference in adverse effects. During analysis, it was determined that the pain reduction variables could be compared by age and body weight using Pearson correlations. Additionally, the pain reduction variables will be compared by gender, duration of pain (\leq 24 hours vs. $>$ 24 hours), and location of pain (back/neck vs. other locations and small vs. large joints) using independent *t*-tests.