

**Double-blind, prospective comparison of medications used in trigger point injections –  
ketorolac, lidocaine, or dexamethasone**

**NCT:** 03028012

**PI:** Dr. Daniel Cushman

**Report Date:** April 5, 2017

**Type of Report:** Statistical Plan/Analysis

This study was terminated early due to the lack of enrollment and of participant follow-through to substantiated end of study measures. There was not enough reported data to provide statistically pertinent or relevant analysis based on the original statistical plan and analysis (listed below). The enrollment for this study consisted of 10 participants, 2 males, 8 females. Out of the total number of participants enrolled only two participants completed all study measurement requirements. The remaining eight participants only completed some of the required protocol surveys. Reviewing this study statistically it was decided that there was not enough statistical data to report statistically significant data.

**Original Statistical plan:**

Chi-square analysis will be used to identify differences in responders between groups. Repeated-measures ANOVA testing will be used to identify changes in pain scores.

**Original Power Analysis:**

Similar to the study by Gerber et al.41, if 5% of patients spontaneously improve their MTrP status without intervention and aiming for detection of 10% responders, a sample size of 90 subjects would be required. However, in their study, they found that this was substantially overpowered due to a much higher percentage of responders. We have identified a sample size of 60 subjects (20 per group) as being sufficient, based on the prior work being overpowered. As they had a much larger response rate in their actual cohort, we feel that a conservative estimate of 15% responders would be appropriate (as opposed to 10%), which yields a sample size around 60 total subjects.