Study Title:
Efficacy of Multimodal Periarticular Injections in Operatively Treated Ankle Fractures: A Randomized Controlled Trial

Date: 8/8/2016

NCT: NCT02967172

Statistical Analysis Plan:

We will compare the two groups by improvement in the following measures:

Visual Analog Scores scores recorded as Standard of Care during daily rounds
Patient controlled analgesia usage as recorded as Standard of Care in Medical Record
Time spent in hospital
Standard of care outcome measures noted in Patient Medical Record

Standard statistical analysis will be performed to analyze differences between groups. ANOVA, T-Test, and Kolmogorov-Smirnov, and other tests will be used.

Based on a power analysis we estimate a minimal sample size of forty patients in each group to detect a 1.5 point difference in the Visual Analog Score (VAS) at each recording, with a standard deviation of 2.0 points, a p-value of .05, and a power of 80% or higher. Additional subjects (total subjects = 200) will aid in subgroup analyses, and ensure that we maintain an adequate sample size even if we run into issues with patient compliance (e.g. refusal of VAS during post-op stay) or unintentional de-blinding (nurse, student, resident etc. accidentally telling patient their treatment assignment) following the procedure.