

COVER PAGE

STATISTICAL ANALYSIS PLAN

Study:

An Integrated-Delivery-of-Care Approach to Improve Patient Outcomes, Safety, Well-Being After Orthopaedic Trauma

NCT Number:

NCT02591472

Document Date:

May 15, 2017

Statistical Analysis: The Statistical package for the Social Sciences (SPSS, v 22.0; Chicago, IL) will be used for analysis. Descriptive statistics will be calculated on categorical study variables and demographics (means and standard deviations for continuous variables, frequencies and percentages for categorical variables). Chi-square for frequency distributions will be used for patient satisfaction to test main effects of time and treatment and their interaction, on patient satisfaction; however, because patient satisfaction will only be measured at the end, a standard general linear model will be used. The primary analyses for all aims will utilize a mixed model repeated measures approach. These analyses can assess the main effects of treatment and time on outcomes, as well as their interaction (treatment x time). Specifically, independent variables will include care approach (integrated vs standard) and time point (admission, 2 weeks, 6 weeks, 3 weeks, month 6, and 12 months). Dependent variables will include all functional measures (actual and perceived). Mixed models are the preferred approach to analyze data with repeated measures; these models can account for correlation among repeated measurements, flexible time effects, and can handle missing data. Significant interactions between treatment and time would indicate that the change in the outcomes (i.e. slope) was dependent on the patient's treatment group. If a significant interaction is identified, the Preacher method will be used to estimate the magnitude and direction of the interaction. A p value will be established a priori at <0.05 for all statistical tests. Continuous data that are not normally distributed will be transformed prior to analysis. Appropriate multiple testing corrections will be performed to limit Type I error.