Statistical Analysis Plan (SAP)

Steroid Administration for Articular Fractures of the Elbow (SAFE Trial): A Randomized, Controlled Trial of Perioperative Glucocorticoids during Treatment of Intraarticular Elbow Fractures

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Protocol Identification Number:	210125
Clinicaltrials.gov Identifier:	NCT04738318
Version Date	03/09/2021

Statistical analysis plan

Demographics will be compared between each treatment arm in each stratification group for comparison and summary statistics for each treatment arm will be provided. If significant differences exist in patient, injury, or treatment variables, subgroup analysis will be performed. Assumptions for each variable will be assessed for normality using histograms and frequencies and cross tabulation will be tabulated for categorical and ordinal variables. If continuous data is not normally distributed, we will use non-parametric analysis methods. Graphical methods will be used to examine data distributions, identify influential observations, and perform transformations if needed. Prior to hypothesis testing, the data will be screened for errors and missing values using descriptive statistics and histograms. Suspicious values will be confirmed for accuracy and changes will be documented in an appendix. Every effort will be made to minimize missing or incomplete data. Study personnel will follow-up with all providers and patients to collect data. Data will be analyzed in a pragmatic fashion and all collected data will be analyzed.

We will use the open-source statistical package R (R Development Core Team, 2012) and Stata 16 statistical software (StataCorp LLC, 2019, College Station, TX) for analysis. An intention-to-treat analysis will be conducted including all eligible patients as originally randomized. Analysis of each primary and secondary endpoint will be performed with all patients at each follow-up time point. Interactions for fracture-type and treatment group will be modeled at each follow-up time point and if significant, each fracture-type group will be independently analyzed. Multivariable proportional odds models for the Aim 1 dependent variable, range-of-motion, will be performed and multivariable logistic regressions will be performed for Aim 2 outcomes evaluating complications and safety. The Aim 3 dependent variable is continuous MME total and will be analyzed using a multivariable proportional odds model as the total amount consumed for each patient during the post-operative course.