Quell Opioid Reduction and Pain Relief in Patients with Cancer

Statistical Analysis Plan

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Sponsor:

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2.5 Statistical Methods

Initially, a sample size of 20 participants per treatment group (active and sham) was selected to achieve 90% power to find a 20% difference in mean percent change in opioid consumption between the two groups with an estimated standard deviation of 22% and 80% power to detect the same difference with a standard deviation of 19% at a two-sided alpha = 0.05.

Bivariate associations between variables were assessed using statistical methods appropriate for the variable types (Fisher's exact for categorical variables; t-test, ANOVA or non-parametric equivalents for continuous variables). Baseline characteristics (demographics, other morbidities, baseline medication use, pain intensity and quality of life) were compared between the two treatment groups to assess effectiveness of randomization and identify important covariates for multivariable analyses. Associations between demographic variables and primary and secondary endpoints were examined. Sensitivity analyses comparing use of data from all participants with use of participants with complete data only was also performed. Agreement between different measures representing the same variable type (e.g., VAS and SF-MPQ-2) was assessed using correlation analyses.

Multivariable analysis with mixed effect regression models were used to assess the effect of treatment group on the primary and secondary outcomes over repeated measures controlling for potential confounders including opioid dose at baseline and using a group*time interaction term to determine differences in time course by treatment. Similar models were used to assess associations of treatment group with the secondary endpoints. Model fit assessed by Akaike's Information Criteria was used to determine the optimal covariance structure.

All statistical analyses were performed using SAS 9.2 (Cary, North Carolina).