Title of Study: Auricular Percutaneous Electrical Nerve Field Stimulation for Postoperative Pain Control in Adults

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Auricular Percutaneous Electrical Nerve Field Stimulation for Postoperative Pain Control in Adults

Statistical analysis plan

Missing Data Handling

Every effort will be made to avoid missing data. Using logistic regression (LR), the assumption of missing at random data will be explored. If the data appear missing at random (MAR), multiple imputations for items and longitudinally random effects models will be used. If missing data appear not random, a sensitivity analysis will be employed, using clinical information and different assumptions to substitute values and see how results are affected.

Patient Demographics and Characteristics Data

Patient characteristics at baseline, demographic and disease characteristics will be summarized using descriptive statistics. In addition, previous and concomitant diseases and medications will be summarized. Frequencies will be presented for the categorical variables (e.g. race) and descriptive statistics will be presented for continuous variables (e.g. age).

Efficacy Variables

Aim 1 (Primary): To determine if auricular neurostimulation uces visual analog pain scores and promotes decreased opioid usage, as measured by total hospital narcotic requirement in oral morphine equivalents.

Aim 2: To determine if auricular neurostimulation is associated with decreased postoperative nausea and vomiting, postoperative ileus, respiratory depression, and length of hospital stay.

Aim 3: To determine if auricular neurostimulation alters the biologic response to surgery.

Statistical Method

All efficacy data will be analyzed including modified intention to treat (mITT) patients. Per-protocol analysis will be done only if more than 10% of the ITT patients do not qualify for the per-protocol analysis. For all efficacy variables, the baseline value will be defined as the last value taken prior to the start of randomized study.

Continuous/Ordinal variables

Summary statistics such as mean, median, standard deviation, range and correlation plots and tree analysis will be used to examine distributions and interrelationships. Where necessary, for parametric assumption, we will employ appropriate transformations with justifications and compare using Student's t-test. If data cannot be appropriately transformed, we will compare variables between the two groups using a Mann-Whitney test. Pain scores will be analyzed using area under the curve for the entire hospitalization.

Categorical variables

We will compare the two groups using a chi - square or Fisher-Haltom exact test.

Power

For the efficacy outcomes, the main comparison of interest is total hospital narcotic requirement in oral morphine equivalents. For simplicity in power calculations, we use a (conservative) two sample two-sided t-test at an alpha of 0.05 on the change. For a power of 90%, assuming a 25% decrease in narcotic consumption with an average total hospital narcotic consumption of 180 mEq oral morphine log-transformed for normal distribution to 2.3 with standard deviation of 0.58, we would require 25 patients per group. Assuming a dropout rate of 10%, we estimate 28 participants in each group will be needed.

Safety Data

All safety variables (e.g., adverse events) will be summarized for each group (including follow-up) using descriptive statistics. Incidence of adverse events will be summarized by treatment.