TENS and Opioid Use After Cesarean Delivery

NCT03843788

Document Type: Statistical Analysis Plan

Document Date: 7/11/2024

Statistical Analysis Plan

All outcomes will be presented using descriptive statistics; normally distributed data by the mean and standard deviation (SD) and skewed distributions by the median and interquartile range (IQR).

Primary Outcome

The primary analysis will compare intervention groups (TENS vs usual care) on mean change in pain score as measured by Visual Analog Scale (VAS) over the course of the inpatient hospital stay. Measured primary outcomes were pain ratings, number and type of pain medications used, and patient satisfaction with pain control. Fixed effects repeated measures analysis of variance was used to evaluate the differences in pain scores between groups and Mann-Whitney tests were used to examine differences in medication intake. Additionally, repeated measures correlation (RMCORR) between TENS and usual care arms with an exploratory analysis of pain behavior in individuals with SUD compared to no SUD will be performed.

Secondary outcomes

Secondary outcomes will include pain surveys at 6 weeks postoperatively, time to first bowel movement, level of sedation, and time to out-of-bed (OOB).

Missing data

Mixed-effects procedure was utilized to avoid loss of data from missing values at different time points.