Department of Biostatistics and Epidemiology
School of Public Health
683 Hoes Lane West
Piscataway, NJ 08854

sph.rutgers.edu
p.732-235-4646
f. 732-235-5476

RUTGERS
School of Public Health

October 12, 2022

Official Title:
Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?

Document: Statistical Analysis Plan

NCT02960113

Comments:

The methods below are consistent with those mentioned in the protocol, after eliminating mention of unneeded procedures for looking at effectiveness of treatment. The methods also clarify the adjustment for multiple testing on the two primary outcomes.

Methods
Means (standard deviations) were used to describe the distributions of continuous variables while frequencies (percentages) were used for categorical variables. Using intent-to-treat analyses, Analysis of Variance (ANOVA) was used to summarize the effect of treatment on satisfaction scores as well as ratings of nausea at time points 1 through 4 while chi-square was used for occurrence (yes/no) of nausea and vomiting overall all time points and vomiting at time points 1 through 4.

A Bonferroni corrected p-value was calculated for the treatment effect on the two main outcomes, presence of vomiting and presence of nausea, such that an adjusted p-value from each test equaled the nominal p-value multiplied by 2.