**Document Title:** Statistical Analysis Plan

**Official Title:** Transcutaneous Auricular Vagus Nerve Stimulation for the Prevention of Emergence Agitation and Emergence Delirium After Adenotonsillectomy in Children: A Randomized, Double-Blind, Interventional Study

**NCT Number:** Not yet assigned

**Date:** August 15, 2024

## Statistical Analysis

All statistical analyses will be performed using SPSS version 26.0. All tests will be two-tailed, and a P value < 0.05 will be considered statistically significant. For continuous variables, data with a normal distribution will be expressed as the mean ± standard deviation (SD), while non-normally distributed data will be presented as median (interquartile range, IQR). For categorical variables, data will be expressed as frequency (n) and percentage (%). For the primary outcome, the incidence of emergence delirium (ED) will be compared between the active stimulation and sham stimulation groups using the Chi-square test ($\chi^2$ test). If any expected frequency is <5, the Fisher's exact test will be applied. To further verify the results, a logistic regression model will be used to assess the association between active taVNS stimulation and the risk of ED, adjusting for potential confounding factors such as age, sex, and surgery duration.

For the secondary outcomes, the Chi-square test or Fisher's exact test will be used to compare the incidence of postoperative pain (FLACC ≥4) and adverse events between the two groups at different time points. For comparisons of PedSQoR scores and recovery time, if the data are normally distributed, an independent-samples t-test will be applied; otherwise, the Mann–Whitney U test will be used.