The Effect of Gentamicin Intravesical Instillations on Decreasing Urinary Tract Infections in Patients with Neurogenic Bladder after SCI: A Clinical Trial

National Clinical Trial (NCT) Identified Number: 03503513

Statistical Analysis Plan

6/23/2023

Statistical Analysis Plan

All data were examined for completeness and outliers before hypothesis testing. Categorical data was summarized in terms of frequencies, presented as n (%), and continuous data will be summarized in terms of means (standard deviations). Participant demographics and clinical status were evaluated using descriptive statistics. All efforts were made to recruit a balanced sample representative of persons with SCI/D. Statistical significance was set at $p < 0.05$ for group comparisons with a 95% confidence interval.

To test for significant differences in the incidence of UTIs across periods (six months pre-treatment, six-month treatment, one-month post-treatment, six months post-treatment) an incidence rate per person month was determined by comparing the total number of UTIs in relation to duration, reflecting all participants across six months. The incidence rate ratio was determined by comparing the different timepoint ratios in relation to pre-treatment ratio. Confidence intervals and p values were calculated for rates and rate ratios. This approach analytical was used to satisfy small sample size calculations, as appropriate with count outcomes data (Hypothesis 1). To assess the impact of the study intervention on our Secondary Endpoint, bladder, and bowel complications (Hypothesis 2), and Tertiary Endpoints, QOL (Hypothesis 3), paired t tests were used to test differences in scores across survey measures.