Title: Electrical Stimulation Therapy for Preventing Hospital-acquired Weakness in Critically III COVID-19 Patients - A Proof of Concept Randomized Controlled Trial

Identifier: NCT04685213

Date: May 21, 2021

Statistical analysis plan

Shapiro-Wilk test (p > 0.05) was used to assess the normality of data. Independent t-test was used for group comparison at baseline on normally distributed continuous demographics, clinical data, and sEMG parameters. Mann-Whitney U test was used if the assumption of normal distribution was not satisfied. For categorical variables, Chi-square test was used to compare between-group differences at baseline. The effect size for baseline continuous and categorical data were measured using Cramer's V and Cohen's d, respectively. Generalized estimating equations (GEE) was used to test the main effect of group (two levels: CG and IG), time (three levels: baseline, 3 days, and 9 days), and their interaction on the outcome measures regardless of data unable to obtain due to the patients' critical condition. Pearson correlation was used to associate baseline values with %change of outcomes at 9 days. For those significant associations, multiple linear regression was used to determine the relationship between those significantly associated variables. The model performance was reported in terms of variance (R2), and p-value. For all tests, an alpha level of < 0.05 was considered statistically significant.