

Transspinal versus Epidural Stimulation for  
Exoskeletal Assisted Walking after Spinal Cord Injury

NCT04241250

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## Statistical Plan

Based on the pilot nature of the trial, mean  $\pm$  SD will be reported for each group and the effect size will be calculated based on the changes compared to baseline measurements. To assess the preliminary effectiveness of the intervention, we will estimate the mean (or median) change of the following variables at different time points and follow-up time point: six-minute walk test, 10-meter walk distance tests, exoskeleton assistance level, surface electromyography measurements, and other secondary measurements. For every outcome, we will also examine the mean difference in change between the EAW+ES and EAW+TS groups with their corresponding 95% confidence intervals. These values will be compared to minimum clinically meaningful effects to determine preliminary efficacy. Lastly, we will estimate the variance of each outcome at the follow-up time points. These values, along with clinically meaningful effects, will be used to determine the sample size required for a future randomized control trial. Given the goal of the trial is to pilot the intervention, and establish preliminary effectiveness, and not designed to confirm the effectiveness of the intervention, we do not propose inferential statistics. Rather the estimates and data gathered from this trial will be used to inform the design of the future confirmatory trial and to show a "signal" that the intervention can provide clinically meaningful changes. All analysis will be completed using the SPSS statistical software.