STATISTICAL ANALYSIS PLAN

STUDY TITLE: ISCHEMIC CONDITIONING CHRONIC STROKE STUDY

DATE OF DOCUMENT: 7/26/2019

Statistical Design and Analysis

We will enroll 15 participants in this study based on both the power analysis listed below and a litany of similar studies with enrollments between 10-20 patients. We will compare the absolute change in plasma catecholamines from immediately after IC or IC Sham to immediately after the CPT (i.e. the change in concentration from rest to immediately after the cold pressor test; comparison is deltaIC vs. deltaIC Sham). Standard deviation of the difference between IC and IC Sham conditions is bounded by 149 pg/ml (=SQRT(2)*SD of delta) based on a study which examined the changes in norepinephrine levels following the CPT in 15 heart failure patients, where SD of delta = 105.55 pg/ml. Under this conservative assumption, the detectible difference with 80% power (ALPHA=0.05) is 116 pg/ml with n=15. A paired t-test will be used to make this comparison. If Shapiro-Wilks test rejects the assumption of normality, we will use exact Wilcoxon signed rank test on non-normally distributed data. Plasma epinephrine concentrations and changes in systolic blood pressure will be compared similarly.