

STUDY TITLE: Intraoperative monitoring and management protocol to reduce strokes

(IMMPRES): Pilot study

IRB: STUDY20070328

NCT04543838

Statistical Analysis: 10/06/2020

Statistical Analysis:

This study will attempt to improve over previous work (summarized in meta-analysis: [J Am Heart Assoc. 2019 May 7;8(9): e010920]), which predominantly used overt and covert strokes as (binary) outcome measures. Drawing from the reported incidence of covert stroke of 33% and anticipating a reduction to 11% in the intervention group, we calculate a power of 78% with 40 subjects per group ($\alpha = 0.05$, calculations in SamplePower, ver 3, SPSS/IBM). The use of a composite primary outcome serves to bolster the power calculation and proposed pilot sample size.

However, we expect to need far fewer patients to show a significant effect in the tertiary outcome related to DWI lesions, for two important reasons. First, a great deal of previous work has been done at low MRI field strength, predominantly 1.5 T. We will utilize 3 T field and modern 32/64 channel head coils with multiband imaging sequences, which will improve DWI resolution and signal to noise ratio. Second, we will count the number of DWI lesions and measure their total volume in the MRI images, providing a more granular (continuous) measure to compare between study groups. As DWI lesions are a known mediator of clinically symptomatic strokes, even showing a small but statistically significant change in number or extent of DWI lesions should provide proof of concept that the IMMPRES intervention is worth further exploration in a fully-powered (externally funded) clinical trial