

Cerebrovascular Imaging Project (CIP)

Statistical Analysis Plan

Primary statistical test

- Significance level of correlation between NiRS measure of compliance and TCD measure of compliance

Secondary statistical tests

- Correlation between compliance (TCD-derived) and cardiorespiratory fitness level
- Correlation between compliance (NiRS-derived) and cardiorespiratory fitness level
- Correlation between compliance (TCD-derived) on left and right MCA

Estimation of total number of subjects required for the primary statistical test based on published data.

The estimated correlation is $r(tcd, nirs) = 0.49$ to 0.62 . Total sample size required when using the correlation coefficient can be formulated as [1]:

$$N = \left[\frac{Z_{\alpha} + Z_{\beta}}{C} \right]^2 + 3$$

Where $Z_{\alpha} = 2.58$ (for $\alpha = 0.01$) and $Z_{\beta} = 0.84$ (for $\beta = 0.20$) are the standard normal deviate for α and β , respectively, $C = 0.5 \times \ln[(1 + r)/(1 - r)]$ and N total number of subjects required.

Our primary measure will be a comparison of NIRS and TCD. Published comparisons of NIRS and TCD on blood flow related measures show correlation with effect sizes, r , reported between 0.49 and 0.62. Given an expected effect size at the average of $r=0.55$ the number of samples required to achieve significance at the $p=0.01$ level is $n=34$. At the lowest correlation coefficient, $r= 0.49$, $n=30$ is sufficient to obtain significance at the $p=0.05$ level. To buffer against any other drop outs we will recruit $n=35$ participants.

[1] Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D., & Newman, T. B. (2013), "Designing clinical research", 4thEd, Appendix 6C