

**Official title: Statin-associated muscle symptoms: in vivo and in vitro studies of mitochondrial function**

**NCT number: NCT04507373**

**Document date: 7/7/2016**

## Statistical Analysis

The primary endpoint will be the differences in pre- and post-phosphocreatine relaxation time in SAMS patients on simvastatin compared to placebo. We chose 15 patients/arm since this sample size is within the range of prior pilot and feasibility studies. The treatment effect will be estimated by comparing the changes in the patient's pre- and post-phosphocreatine relaxation between the experimental and control arm using the independent t-test. All analyses will be conducted according to the intention-to-treat principle. Significance: A p-value of less than 0.05 will be considered statistically significant. Multiple testing correction will not be applied as this is a pilot study.