

Cover Page for Statistical Analysis Plan

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Linear mixed model analysis for repeated measures will be used to test for change over the follow-up period in the primary outcome measures. Post-hoc pairwise comparison with baseline will be performed using Dunnett's test. Mean estimates at each time point, and mean change from baseline (with 95% confidence limits) will be computed from the fitted model. All tests were two-tailed and a $p < 0.05$ was considered as statistically significant. All analyses will be conducted using the intention-to-treat population.