

Comparing NGENUITY vs Conventional Microscope in a New Hydrus User

Statistical Analysis Plan

NCT05529966

March 14, 2025

The original planned sample size for this study was 32 participants, with each participant enrolling a single study eye. However, it was later determined that if both eyes of a participant were eligible for the study, the same participant could be enrolled for their second eye surgery, resulting in a revised planned sample size of a total of 32 eyes. Additionally, the study protocol was modified to include a total of three glaucoma fellows participating in the surgeries, rather than the originally planned two. To analyze the outcome measures, a two-tailed t-test with two-sample unequal variance was used for primary and secondary outcomes with both NGENUITY and convention microscope groups. After Bonferroni correction, the new threshold for statistical significance was <0.002083333 .