Randomized Trial of High Dose vs. Standard Dose Influenza Vaccine in Inflammatory Bowel Disease Patients

Protocol: Statistical Plan August 13, 2015.

Statistical methods and power calculations

Antibody concentrations between groups were compared using nonparametric tests, Mann-Whitney U or Kruskall-Wallis tests. Seroprotection and seroconversion rates between groups were compared using Chi-square or Fisher's Exact tests.

For our primary objective, we prospectively calculated our sample sized based on Hagihara et al (patients with IBD) and Falsey et al (high dose influenza vaccine) to inform our estimates. [8, 16] These two studies provided the basis for our antibody concentration estimates for the sample size calculation. Forty individuals with IBD were planned (25 randomized to HD and 15 randomized to SD vaccine) to yield a power 89% to detect a difference in A/H3N2 antibody concentrations of 47 + 25 in the SD group and 80 + 40 in the high dose group. This sample size yielded a 93% power to detect a significant difference in A/H1N1 antibody concentrations (SD 80+40 and HD 140+70).The vedolizumab arm of the study was considered exploratory, and no power calculation was done.