Statistical Analysis Plan

Pilot Study Evaluating the Efficacy of Certolizumab Pegol for Interstitial

Sample size

Previous IC/BPS studies demonstrated an approximate 20% placebo response rate [29]. Monotherapy response rate of certolizumab pegol in rheumatoid arthritis was 45% [21]. To achieve an 80% power using 2:1 randomization and a 2-sided $p = .05$ a minimum of 39 subjects was required. The sample size was increased by 3 subjects to account for potential participant withdrawals.

Randomization

Eligible participants were computer randomized and received either subcutaneous certolizumab pegol 400gm or placebo (sterile saline) in a 2:1 ratio at weeks 0, 2, 4, and 8. The study drug and placebo were provided in ready to use syringes that were identical other than the blinded ID number on the side of the syringe.

Statistical analysis

Any patient who withdrew from the study, for whatever reason, was classified as a non-responder.

All statistical summaries and 2-sample t-tests were performed using the Data Desk® version 6.3. Comparison of these changes between treatment groups are also shown as 95% confidence intervals (CI). The chi-square test or Fisher's exact test was applied to analyze baseline demographics, improvement with GRA treatment responders, and the proportion of patients with a reduction from baseline of 30% or greater in their pain intensity score between treatment groups.