**Effect of Aerosolized Antibiotic Therapy on FEV1 in Cystic Fibrosis Patients with Pulmonary Infection**

**Background:** Cystic Fibrosis (CF) is a genetic disorder that affects about 30,000 people in the US. It is a serious condition that is complicated by recurrent pulmonary infection. A two-arm placebo-controlled double-blind randomized study was conducted in CF patients age 10-60 with infections to investigate the effect of an aerosolized antibiotic therapy on forced expiratory volume in one second (FEV1), a measure of pulmonary function. FEV1 was measured before randomization and at the end of the study (24 weeks later).

**Approach:** The distribution of the change in FEV1 was investigated through graphical measures and summary statistics. A Wilcoxon rank-sum test was conducted to determine if the treatment group had significantly different change in FEV1 than the placebo group.

**Results:** The median change in FEV1 over the course of the study in the treatment (N = 258) and placebo (N = 262) groups were 0.03 (IQR = 0.31) and 0.00 (IQR = 0.25), respectively. The range in the treatment group was -0.71 to 1.44, and the range in the placebo group was -0.93 to 1.37. Based on the Wilcoxon Rank-Sum test, there is very strong evidence of a difference in change in FEV1 between treatment and placebo (p-value < 0.0001, W = 41413).

**Conclusions:** There is evidence to suggest the treatment group resulted in a larger increase in FEV1, suggesting the therapy improved pulmonary function among CF patients with pulmonary infection. Figure 1 shows the distributions of change in FEV1 are very similar for treatment vs placebo, and the difference in medians is 0.03. While there are statistically significant differences in the groups, the clinical significance should be discussed with a physician.

