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BIOS 718

Homework 1

**Background:** Cystic fibrosis (CF) is a serious genetic disorder that affects about 30,000 people in the United States. Recurrent pulmonary infection caused by the pseudomonas aruginosa bacterial strain is a common complication of CF. A study was conducted to determine if individuals with CF could be effectively treated for infection with aerosolized antibiotic therapy. The study was a double-blind controlled trial where 520 CF patients aged 10 to 60 years were randomized to receive the active treatment or placebo. The pulmonary function test forced expiratory volume in one second (FEV1) was the primary endpoint.

**Approach:** Measurements were collected before patients were randomized and again at the conclusion of the 24-week study. The change in FEV1 score from the beginning of the trial to the end of the trial was calculated for each patient. The change in FEV1 score variable was not normally distributed. ANCOVA was chosen to test for difference in change in FEV1 because ANCOVA is fairly robust to non-normality and the distribution is not extremely far off from a normal distribution.

**Results:** An ANCOVA model was run to determine if initial FEV1 score affected change in FEV1 score when accounting for treatment type. Treatment type was found to be significant (p-value < 0.001) in the ANCOVA model, while initial FEV1 score was found to be borderline significant (p-value 0.05).

**Conclusions:** Aerosolized antibiotic therapy was effective in treating infection in individuals with CF. More research can be done, however, to determine how baseline FEV1 score affects follow-up FEV1 score when using this treatment.

Table 1

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