The six-minute walk test (6MWT) is used for the objective evaluation of functional exercise capacity. 

**INTRODUCTION**

The increasing prevalence of pulmonary disease caused by nontuberculous mycobacteria (NTM) lung infections is an emerging public health concern worldwide. The six-minute walk test (6MWT) is a practical, simple test that measures the distance that a patient can walk in a period of 6 minutes. 

**STUDY DISPOSITION**

**Patient Characteristics**

- Of 124 randomized patients, 90 were randomized to double-blind treatment (39% CF; 81% MAC; 40% with Mycobacterium avium complex [MAC] infection; and 30% with M. abscessus infection). The 90 patients were included in the efficacy evaluation set (89 completed the double-blind phase; 1 declined participation in open-label treatment) (Table 1).

- There was no significant difference in the LS mean change from baseline to Day 84 in the 6MWT distance walked for patients with culture conversion (n = 20); however, there was a nonsignificant trend toward increased distance walked in patients with culture conversion (n = 26) (Figure 3).

- A significant difference was not seen in the LS mean change from baseline to Day 84 in distance walked in the 6MWT (Figure 3).

- There was a significant difference seen in the LS mean change for the 6MWT distance walked for patients with MAC infection (37.3 m vs. 0.5 m; P = 0.002) (Figure 3).

- The primary endpoint of change from baseline in the full semiquantitative scale did not achieve statistical significance, although there was a trend in favor of the LAI arm. The primary analysis of conversion (ie, 3 consecutive negative sputum samples collected 1 month apart) in patients with NTM lung infection refractory to guideline-based therapy was further supported at each time point with at least one and in most cases two additional sputum cultures.

- Appropriate categorization of these specimens does affect the efficacy outcomes such that the drug now appears to be more effective than was originally reported.

**RESULTS**

**Culture Results**

- The proportion achieving culture conversion was not significantly different across the open-label treatment arms. 

- Culture conversion was determined by coughing up expectoration, which was sent for mycobacterial culture in liquid media. The preliminary results included analysis of all patients who contributed their time and faith to participate in the study.

- There was no significant difference in the LS mean change from baseline to Day 84 in distance walked in the 6MWT (Figure 3).

- The six-minute walk test is an important tool in clinical trials sponsored by Aradigm Corporation and Insmed Incorporated. Kevin L. Winthrop is involved in clinical trials sponsored by Insmed Incorporated. Daniel Dorgan has no disclosures.

**CONCLUSIONS**

- Patients with NTM lung infections refractory to treatment showed improved in distance walked in the 6MWT when LAI was added to their background of guideline-based therapy.

- The inclusion of these toxicities in the study allowed for the study of adverse events of pharmacological treatment as assessed by the 6MWT, which was conducted when patients were unaware of their culture results. This supports the hypothesis that pharmacological treatment can affect study outcomes.

**REFERENCES**


