

primary studies - published RCT

## **Dornase alfa during lower respiratory tract infection post-lung transplantation: a randomized controlled trial.**

**Code:** PM30632208

**Year:** 2019 **Date:**

**Author:** Tarrant BJ

### **Study design (if review, criteria of inclusion for studies)**

Double-blind, phase 3b study

### **Participants**

People with cystic fibrosis (pwCF) with newly isolated *Pseudomonas aeruginosa* (Pa). 149 participants were randomized and 142 (95.3%) completed treatment. Median age: 6.0 years (range: 0.3-17.0).

### **Interventions**

Participants were randomized to receive 75 mg AZLI three times daily for either 28 or 14 days followed by 14 days' matched placebo.

### **Outcome measures**

The primary endpoint was rate of primary Pa eradication (no Pa detected during the 4 weeks post AZLI treatment). Non-inferiority was achieved if the lower 95% CI bound of the treatment difference between the two arms was above -20%. Secondary endpoints included assessments of Pa recurrence during 108 weeks of follow-up after primary eradication. Safety endpoints included treatment-emergent adverse events (TEAEs).

### **Main results**

In total, 149 participants were randomized (14-day AZLI, n = 74; 28-day AZLI, n = 75) and 142 (95.3%) completed treatment. Primary Pa eradication rates: 14-day AZLI, 55.9%; 28-day AZLI, 63.4%; treatment difference (CI), -8.0% (-24.6, 8.6%). Pa recurrence rates at follow-up end: 14-day AZLI, 54.1% (n = 20/37); 28-day AZLI, 41.9% (n = 18/43). TEAEs were similar between treatment arms. No new safety signals were observed.

### **Authors' conclusions**

Non-inferiority of 14-day AZLI versus 28-day AZLI was not demonstrated. Both courses were well tolerated, further supporting AZLI short-term safety in paediatric and adolescent pwCF.

<http://dx.doi.org/10.1111/tri.13400>

### **See also**

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### **Keywords**

Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Colonization; Infection; Inhalation OR nebulised; pharmacological\_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Monobactams;