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primary studies - published RCT

## **A phase 2 study of aztreonam lysine for inhalation to treat patients with cystic fibrosis and Pseudomonas aeruginosa infection.**

**Code:** PM18041081

**Year:** 2008 **Date:** 2008

**Author:** Retsch-Bogart GZ

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

double-blind, randomized, placebo-controlled Phase 2 study

### **Participants**

Patients were 13 years and older with FEV1  $\geq$  40% predicted, chronic *P. aeruginosa* infection, and had used no anti-pseudomonal antibiotics for 56 days. Of 131 patients screened, 105 received AZLI or placebo. Mean age was 26 years and mean FEV1 percent predicted was 77% at baseline.

### **Interventions**

75 and 225 mg AZLI administered BID for 14 days using the eFlow Electronic Nebulizer (Pari Innovative Manufacturers, Inc., Midlothian, VA)

### **Outcome measures**

*P. aeruginosa* CFU density, FEV1, plasma aztreonam concentrations, Adverse events

### **Main results**

There was a statistically significant reduction, compared to placebo, in *P. aeruginosa* CFU density in each AZLI group at Days 7 and 14 (P

### **Authors' conclusions**

These data support the further development of AZLI and provide information for the design of subsequent studies.

<http://dx.doi.org/10.1002/ppul.20736>

### **See also**

Pediatr Pulmonol. 2008 Jan;43(1):47-58.

### **Keywords**

Adolescent; Adult; Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Supplementation; Monobactams;