

primary studies - published RCT

## Efficacy and safety of inhaled aztreonam lysine for airway pseudomonas in cystic fibrosis.

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

randomized, double-blind, placebo-controlled, international study (AIR-CF1 trial; June 2005 to April 2007)

### Participants

CF patients (n = 164;  $\geq 6$  years of age) with FEV(1)  $\geq 25\%$  and

### Interventions

patients were treated with 75 mg of AZLI (three times daily for 28 days) or placebo (1:1 randomization), then were monitored for 14 days after study drug completion.

### Outcome measures

The primary efficacy end point was change in patient-reported respiratory symptoms (CF-Questionnaire-Revised [CFQ-R] Respiratory Scale). Secondary end points included changes in pulmonary function (FEV(1)), sputum PA density, and nonrespiratory CFQ-R scales. Adverse events and minimum inhibitory concentrations of aztreonam for PA were monitored.

### Main results

After 28 days of treatment, AZLI improved the mean CFQ-R respiratory score (9.7 points; p

### Authors' conclusions

In patients with CF, PA airway infection, moderate-to-severe lung disease, and no recent use of antipseudomonal antibiotics or azithromycin, 28-day treatment with AZLI significantly improved respiratory symptoms and pulmonary function, and was well tolerated.

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### See also

Chest. 2009 May;135(5):1223-32.

### Keywords

Adolescent; Adult; Aged; Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Child; Infection; Inhalation OR nebulised; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Supplementation; Monobactams;