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>or=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.

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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;