primary studies - published RCT

Inhaled aztreonam lysine for chronic airway Pseudomonas aeruginosa in cystic fibrosis.

Code: PM18658109 **Year:** 2008 **Date:** 2008 **Author:** McCoy KS

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

randomized, double-blind, placebo-controlled study

Participants

patients with CF.

Interventions

After randomization and a 28-day course of tobramycin inhalation solution (TIS), patients (n = 211; > or =6 yr; > or =3 TIS courses within previous year; FEV(1) > or = 25% and

Outcome measures

The primary efficacy endpoint was time to need for additional inhaled or intravenous antipseudomonal antibiotics. Secondary endpoints included changes in respiratory symptoms (CF Questionnaire-Revised [CFQ-R] Respiratory Scale), pulmonary function (FEV(1)), and sputum PA density. Adverse events and minimum inhibitory concentrations of aztreonam for PA were monitored.

Main results

AZLI treatment increased median time to need for additional antipseudomonal antibiotics for symptoms of pulmonary exacerbation by 21 days, compared with placebo (AZLI, 92 d; placebo, 71 d; P = 0.007). AZLI improved mean CFQ-R respiratory scores (5.01 points, P = 0.02), FEV(1) (6.3%, P = 0.001), and sputum PA density (-0.66 log(10) cfu/g, P = 0.006) compared with placebo; no AZLI dose-response was observed. Adverse events reported for AZLI and placebo were comparable and consistent with CF lung disease. Susceptibility of PA to aztreonam at baseline and end of therapy were similar.

Authors' conclusions

AZLI was effective in patients with CF using frequent TIS therapy. AZLI delayed time to need for inhaled or intravenous antipseudomonal antibiotics, improved respiratory symptoms and pulmonary function, and was well tolerated.

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See also

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Keywords

Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Child; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Supplementation; Monobactams;