primary studies - published RCT

Microbiology, safety, and pharmacokinetics of aztreonam lysinate for inhalation in patients with cystic fibrosis.

Code: PM16703579 **Year:** 2006 **Date:** 2006 **Author:** Gibson RL

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

double-blind, placebo-controlled, dose-escalation trial

Participants

12 adults and 12 adolescent patients

Interventions

Single daily escalating doses of AI 75, 150, or 225 mg, or placebo were self-administered using an eFlow Electronic Nebulizer.

Outcome measures

Sputum samples were collected up to 4 hr and blood samples up to 8 hr post-dose.

Main results

AI activity against multiple CF isolates was retained after nebulization via eFlow, and activity was not inhibited by CF sputum. All 12 adult subjects and 11/12 adolescents tolerated all AI doses. One patient had an asymptomatic FEV1 decrease > 20% with the 150 mg dose. Median aztreonam sputum concentrations in adults 10 min after AI 75, 150, and 225 mg were 383, 879, and 985 microg/g, respectively. Median sputum concentrations in adolescents 10 min after AI 75, 150, and 225 mg were 324, 387, and 260 microg/g, respectively. Systemic exposure to AI was low. Plasma pharmacokinetics in adults receiving AI 75 mg were Cmax = 419 ng/g, Tmax = 0.99 hr, t1/2 = 2.1 hr. Aztreonam concentrations in sputum were at or above the MIC50 for at least 4 hr post-dose.

Authors' conclusions

These data support the continued development of AI for treatment of pulmonary infections in patients with CF.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Aztreonam; Inhalation OR nebulised; pharmacological_intervention; Supplementation; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Pseudomonas aeruginosa; Pseudomonas; Dose-Escalating; Self-Management; Monobactams;