primary studies - published RCT

An 18-month study of the safety and efficacy of repeated courses of inhaled aztreonam lysine in cystic fibrosis.

Code: PM20672296 **Year:** 2010 **Date:** 2010 **Author:** Oermann CM

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

AIR-CF3 was an international 18-month, open-label study

Participants

patients aged >/=6 years with CF and PA infection who previously participated in one of two Phase 3 studies: AIR-CF1 or AIR-CF2. 274 patients, mean age 28.5 years (range: 8-74 years), participated.

Interventions

Patients received up to nine courses (28 days on/28 days off) of 75 mg AZLI two (BID) or three times daily (TID) based on randomization in the previous trials.

Outcome measures

Mean treatment adherence - Hospitalization rates - FEV(1) and scores on the Cystic Fibrosis Questionnaire-Revised Respiratory Symptom - bacterial density in sputum

Main results

Mean treatment adherence was high (92.0% BID group, 88.0% TID group). Hospitalization rates were low and adverse events were consistent with CF. With each course of AZLI, FEV(1) and scores on the Cystic Fibrosis Questionnaire-Revised Respiratory Symptom scale improved and bacterial density in sputum was reduced. Benefits waned in the 28 days off therapy, but weight gain was sustained over the 18 months. There were no sustained decreases in PA susceptibility. A dose response was observed; AZLI TID-treated patients demonstrated greater improvements in lung function and respiratory symptoms over 18 months. Repeated intermittent 28-day courses of AZLI treatment were well tolerated. Clinical benefits in pulmonary function, health-related quality of life, and weight were observed with each course of therapy.

Authors' conclusions

AZLI is a safe and effective new therapy in patients with CF and PA airway infection.

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See also

Pediatr Pulmonol. 2010 Nov;45(11):1121-34.

Keywords

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