primary studies - published RCT

The impact of behavioral intervention on family interactions at mealtime in pediatric cystic fibrosis.

Code: CN-00708355 **Year:** 2008 **Date:** 2012 **Author:** Janicke DM

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

Double-blind, placebo-controlled, multicenter study

Participants

Patients greater than or equal to 18 years of age, with CF, chronic Pseudomonas aeruginosa (PA) airway infection, and FEV(1) greater than or equal to 25% and less than or equal to 75% predicted. A total of 119 patients were randomized to FTI (160/40 mg: n = 41; 80/20 mg: n = 38) or placebo (n = 40). Mean age was 32 years and mean FEV(1) was 49% predicted at screening.

Interventions

Fosfomycin/tobramycin for inhalation (FTI) (160/40 mg or 80/20 mg), administered twice daily for 28 days versus placebo. This study assessed whether FTI/placebo maintained FEV(1) % predicted improvements achieved following a 28-day, open-label, run-in course of aztreonam for inhalation solution (AZLI).

Outcome measures

Safety and efficacy of FTI. FEV(1) % [primary endpoint]; PA sputum density; adverse events, primarily cough, dyspnea and wheezing, laboratory values.

Main results

Relative improvements in FEV(1) % predicted achieved by the AZLI run-in were maintained in FTI groups compared with placebo (160/40 mg vs. placebo: 6.2% treatment difference favoring FTI, P = 0.002 [primary endpoint]; 80/20 mg vs. placebo: 7.5% treatment difference favoring FTI, P

Authors' conclusions

FTI maintained the substantial improvements in FEV(1) % predicted achieved during the AZLI run-in and was well tolerated. FTI is a promising antipseudomonal therapy for patients with CF.

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See also

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Keywords

Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Aztreonam; Fosfomycin; Tobramycin; Exacerbation; Aminoglycosides; Monobactams; other anti-bacterial agents;