primary studies - published RCT

Long-term benefits of inhaled tobramycin in adolescent patients with cystic fibrosis.

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

Two identical, randomized, placebo-controlled trials followed by three open-label follow-on trials. 69 CF study centers in the United States.

Participants

128 adolescent CF patients (aged 13 to 17 years) with P aeruginosa and mild-to-moderate lung disease (FEV(1) percent predicted > or = 25% and

Interventions

Active drug consisting of a 300-mg tobramycin solution for inhalation (TSI).

Outcome measures

Pulmonary function, P aeruginosa colony forming unit density, incidence of hospitalization and IV antibiotic use, weight gain, and aminoglycoside toxicity were monitored.

Main results

At the end of the first three 28-day cycles of TSI treatment, patients originally randomized to TSI and placebo treatments exhibited improvements in FEV(1) percent predicted of 13.5% and 9.4%, respectively. FEV(1) percent predicted was maintained above the value at initiation of TSI treatment in both groups. At the end of the last "on-drug" period (92 weeks), patients originally randomized to TSI and placebo treatments showed improvements of 14.3% and 1.8%, respectively. Improvement in pulmonary function was significantly correlated with reduction in P aeruginosa colony forming unit density (p = 0.0001). The average number of hospitalizations and IV antibiotic courses did not increase over time. TSI treatment was associated with increased weight gain and body mass index. P aeruginosa susceptibility to tobramycin decreased slightly over time, but this was not correlated with clinical response.

Authors' conclusions

TSI treatment improved pulmonary function and weight gain in adolescent patients with CF over a 2-year period of long-term, intermittent use.

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See also

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Keywords

Adolescent; Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; pharmacological_intervention; Pneumonia; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;