primary studies - published RCT

Do inhaled corticosteroids impair long-term growth in prepubertal cystic fibrosis patients?

Code: PM16799799 **Year:** 2007 **Date:** 2011 **Author:** De Boeck K

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

randomized, double-blind study

Participants

patients with CF (age 6-21 years)

Interventions

tobramycin inhalation powder (112 mg tobramycin) twice daily (n = 46) or placebo (n = 49) via the T-326 Inhaler for one cycle, followed by two open-label cycles (all patients). Cycles were 28 days on, 28 days off treatment.

Outcome measures

The primary endpoint was change in forced expiratory volume in 1 sec (FEV(1)) % predicted from baseline to Day 28 of Cycle 1.

Main results

The study was terminated early based on positive results in the interim analysis. Tobramycin inhalation powder significantly improved FEV(1) % predicted versus placebo at Day 28 (difference 13.3, 95% CI: 5.31-21.28; P = 0.0016). Similar changes in FEV(1) were seen in patients switching from placebo to tobramycin inhalation powder in Cycle 2; improvements were maintained over time. Tobramycin inhalation powder also reduced sputum P. aeruginosa density, respiratory-related hospitalization and antipseudomonal antibiotic use versus placebo. The most common adverse event was cough; the frequency of cough was higher in patients receiving placebo (26.5%) versus tobramycin inhalation powder (13.0%) in Cycle 1. Tobramycin inhalation powder was not associated with ototoxicity or nephrotoxicity. Administration time was between 4 and 6 min.

Authors' conclusions

tobramycin inhalation powder was effective and well tolerated in CF patients, and may offer an important treatment option to decrease the treatment burden of CF pseudomonas lung infections.

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See also

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Keywords

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