primary studies - published RCT

Tobramycin inhalation powder for P. aeruginosa infection in cystic fibrosis: The EVOLVE trial.

Code: PM20963831 **Year:** 2011 **Date:** 2011 **Author:** Konstan MW

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.

http://dx.doi.org/ 10.1002/ppul.21356

See also

Pediatr Pulmonol. 2010 Oct 20. [Epub ahead of print]

Keywords

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