primary studies - published RCT

Once-daily tobramycin in the treatment of adult patients with cystic fibrosis.

Code: PM11866010 **Year:** 2002 **Date:** 2002 **Author:** Whitehead A

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

RCT

Participants

60 adult CF patients with an acute respiratory exacerbation

Interventions

10 mg x kg(-1) tobramycin once-daily or 3.3 mg x kg(-1) tobramycin thrice-daily.

Outcome measures

Primary efficacy and safety endpoints were defined as changes in respiratory function and changes in renal function and hearing.

Main results

Both groups showed a significant increase in respiratory function without a clinically significant change in renal function. For changes in forced vital capacity % predicted and serum potassium and magnesium levels, equivalence was demonstrated. For the variables forced expiratory volume in one second and forced mid-expiratory flow % pred and serum creatinine levels, there was insufficient power to demonstrate equivalence. One patient in each group showed bilateral impairment in pure tone audiogram after treatment.

Authors' conclusions

This study demonstrated significant clinical improvement with both once- and thrice-daily tobramycin dosing. Equivalence between the two regimens was shown for some, but not all primary endpoints. Once-daily dosing should be used with careful monitoring of safety and efficacy until large multicentre studies confirm these encouraging results.

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See also

Eur Respir J. 2002 Feb;19(2):303-9.

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Drug Administration Schedule; Infection; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Exacerbation; Aminoglycosides;