primary studies - published RCT

A randomised clinical trial of nebulised tobramycin or colistin in cystic fibrosis.

Code: PM12358344 **Year:** 2002 **Date:** 2002 **Author:** Hodson ME

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

Parallel groups. Open label. Random allocation. Startified by age and centre.

Participants

Criteria for diagnosis: abnormal sweat electrolytes, gene mutation. 143 CF people screened, 17 screening failures, 126 randomised, 11 withdrew before treatment, 115 treated (males 45% of total). Age range 7 - 50 years. Exclusion included any anti-pseudomonal antibiotics within the previous 14 days.

Interventions

Tobramycin 300 mg in 5 ml twice daily. Colistin 1MU in 3 ml in saline twice daily. Duration 28 days.

Outcome measures

Lung function (FEV1). Sputum culture for P. aeruginosa, density and MIC. Adverse effects.

Main results

TNS produced a mean 6.7% improvement in lung function (p=0.006), whilst there was no significant improvement in the colistin-treated patients (mean change 0.37%). Both nebulised antibiotic regimens produced a significant decrease in the sputum P. aeruginosa density, and there was no development of highly resistant strains over the course of the study. The safety profile for both nebulised antibiotics was good. Tobramycin nebuliser solution significantly improved lung function of patients with cystic fibrosis chronically infected with Pseudomonas aeruginosa, but colistin did not, in this study of 1-month's duration. Both treatments reduced the bacterial load.

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See also

Eur Respir J. 2002 Sep;20(3):658-64.

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Colistin; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; other anti-bacterial agents; Aminoglycosides;