primary studies - published RCT

Long-term effects of inhaled tobramycin in patients with cystic fibrosis colonized with Pseudomonas aeruginosa.

Code: PM2505216 **Year:** 1989 **Date:** 1989 **Author:** MacLusky IB

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

Parallel group. Single-blinded (investigator). Placebo control.

Participants

Criteria for CF chronic lung disease, pancreatic insufficiency and elevated sweat chloride. 28 participants (14 male). Age range 7 - 24 years. All had P. aeruginosa in sputum culture. Mean baseline FEV1 78% (SD 21) and 70% (SD 22) predicted in treatment groups.

Interventions

Tobramycin 80 mg or normal saline twice daily for mean duration of study of 30 months (saline control) and 33 months (tobramycin).

Outcome measures

Lung function (FEV1 and FVC), clinical scores, sputum culture and sensitivity (24 months), exacerbations (hospitalisation for respiratory deterioration), ototoxicity and renal toxicity.

Main results

No significant differences were found between the two groups at enrollment. The treatment group showed no change, while the control group had a significant decline in both pulmonary function and clinical status over the study period. Individually, 11 of 12 patients in the control group showed deterioration, while 9 of 15 in the treatment group with susceptible P. aeruginosa at enrollment acquired resistant organisms. There was no evidence of significant nephro- or ototoxicity.

Authors' conclusions

Although inhaled tobramycin appeared to arrest the decline in pulmonary status, further work is required to identify patients most likely to respond.

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See also

Pediatr Pulmonol. 1989;7(1):42-8.

Keywords

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