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primary studies - published RCT

## **Intermittent administration of inhaled tobramycin in patients with cystic fibrosis. Cystic Fibrosis Inhaled Tobramycin Study Group.**

**Code:** PM9878641

**Year:** 1999 **Date:** 1999

**Author:** Ramsey BW

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

Random allocation. Double blinded. Placebo control. Parallel groups.

### **Participants**

520 participants (54% male). Age from six years, 54% 18 years or older. All infected with *P. aeruginosa*. Baseline FEV1 25-75% predicted. Criteria for CF were CFF clinical practice guidelines.

### **Interventions**

Tobramycin 300 mg or 0.225 normal saline and 1.25 mg quinine twice daily for three 28-day on-off cycles.

### **Outcome measures**

Lung function (FEV1 and FVC), exacerbations (hospitalisation or IV antibiotics), sputum *P. aeruginosa* colony count, renal toxicity, ototoxicity.

### **Main results**

The patients treated with inhaled tobramycin had an average increase in forced expiratory volume in one second (FEV1) of 10 percent at week 20 as compared with week 0, whereas the patients receiving placebo had a 2 percent decline in FEV1 (P

### **Authors' conclusions**

In a 24-week study of patients with cystic fibrosis, intermittent administration of inhaled tobramycin was well tolerated and improved pulmonary function, decreased the density of *P. aeruginosa* in sputum, and decreased the risk of hospitalization.

<http://dx.doi.org/10.1056/NEJM199901073400104>

### **See also**

N Engl J Med. 1999 Jan 7;340(1):23-30.

### **Keywords**

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Hospitalization; Hospital care; Infection; Inhalation OR nebulised; Intermittent; Intravenous; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;