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primary studies - published RCT

## Significant microbiological effect of inhaled tobramycin in young children with cystic fibrosis.

**Code:** PM12480612

**Year:** 2003 **Date:** 2003

**Author:** Gibson RL

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

double-blind, placebo-controlled, multicenter, randomised trial

### Participants

Positive *P. aeruginosa* culture. 21 participants (11 males) age range 6 months - 6 years.

### Interventions

Tobramycin 300 mg or placebo twice daily for 28 days.

### Outcome measures

Density of *P. aeruginosa* on BAL culture. Adverse effects. Weight.

### Main results

There was a significant difference between treatment groups in the reduction in Pa density; no Pa was detected on Day 28 in 8 of 8 active group patients compared with 1 of 13 placebo group patients. We observed no differences between treatment groups for clinical indices, markers of inflammation, or incidence of adverse events. No abnormalities in serum creatinine or audiometry and no episodes of significant bronchospasm were observed in association with active treatment.

### Authors' conclusions

28 days of tobramycin solution for inhalation of 300 mg twice daily is safe and effective for significant reduction of lower airway Pa density in young children with cystic fibrosis.

<http://dx.doi.org/10.1164/rccm.200208-855OC>

### See also

Am J Respir Crit Care Med. 2003 Mar 15;167(6):841-9. Epub 2002 Dec 12.

### Keywords

Anti-Bacterial Agents; Bacterial Infections; carrier status; Child; Drug Administration Schedule; Genetic Predisposition to Disease; Infection; Inhalation OR nebulised; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;