

### primary studies - published RCT

# A pilot study to compare tobramycin 80 mg injectable preparation with 300 mg solution for inhalation in cystic fibrosis patients.

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

RCT, cross-over design.

# **Participants**

32 participants (15 males, 17 females). Mean age 18.5 (8.6) years. Confirmed diagnosis of CF, with at least 2 positive cultures for P. aeruginosa in the last 6 months and clinically stable. Initially 18 participants took low continual dose and 14 higher intermittent dose.

## Interventions

Inhaled tobramycin (IV-preparation) 80 mg twice daily continuously for 3 months or intermittent (4-weekly on-off cycles) inhaled tobramycin 300 mg for 3 months.

## Outcome measures

FEV1, FVC, participant preference, oxygen saturation.

### Main results

A total of 32 patients with a mean (+/- SD) age of 18.5 (+/-8.6) years were included in the study. Compared with the treatment period using colistin, forced expiratory volume in 1 s decreased by -2.1+/-13.8% in the 80 mg tobramycin group and increased by +2.3+/-13.0% in the 300 mg group. Similar changes were observed in forced vital capacity (-2.5+/-12.9% in the 80 mg tobramycin group versus +2.5+/-9.6% in the 300 mg tobramycin group). Variability in responses was large but the differences were not statistically significant. Personal preference indicated that the majority of patients preferred the high-dose cycle compared with the lower dose continuous inhalation, but this was not linked to objective data on efficacy.

# Authors' conclusions

The present trial fails to provide convincing evidence for superiority in efficacy of either of the two treatment regimens of inhaled tobramycin in CF patients.

# See also

Can Respir J. 2008 Jul-Aug;15(5):259-62.

## Keywords

Adolescent; Adult; Anti-Bacterial Agents; Drug Administration Schedule; Inhalation OR nebulised; Intravenous; pharmacological\_intervention; Tobramycin; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Pseudomonas aeruginosa; Pseudomonas; Continuous; Intermittent; Aminoglycosides;