primary studies - published RCT

Dornase alfa reduces air trapping in children with mild cystic fibrosis lung disease: a quantitative analysis.

Code: PM16236891 **Year:** 2005 **Date:** 2008 **Author:** Robinson TE

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.

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See also

Chest. 2005 Oct;128(4):2327-35.

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;