primary studies - published RCT

Comparison of three jet nebulizer aerosol delivery systems used to administer recombinant human DNase I to patients with cystic fibrosis. The Pulmozyme rhDNase Study Group.

Code: PM7606951 **Year:** 1995 **Date:** 1995 **Author:** Fiel SB

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

Multicenter, randomized, open-label, parallel-group study.

Participants

Outpatient clinics at 26 sites in the United States. 397 patients > 5 years of age with cystic fibrosis and baseline forced vital capacity (FVC) values between 40 and 70% of predicted values.

Interventions

Patients were treated with rhDNase (2.5 mg bid) for 15 days, administered with three different aerosol delivery systems.

Outcome measures

FEV1 and FVC (at baseline, 8 days, 15 days). Adverse events.

Main results

All three nebulizers gave comparable improvements in pulmonary function. FEV1 increased by an average of 13.2 to 14.1%, FVC by 10.9 to 11.8% and forced midexpiratory flow (FEF25-75) by 16.5 to 17.1%. No unusual or unexpected adverse events were reported other than those that would be expected in patients with cystic fibrosis.

Authors' conclusions

Recombinant human DNase I produced a similar magnitude of improvement in the pulmonary function of patients with cystic fibrosis when the drug was administered using three different types of nebulizer systems with similar in vitro delivery and safety characteristics.

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See also

Chest. 1995 Jul;108(1):153-6.

Keywords

Adult; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Recombinant Proteins; Respiratory System Agents; Dornase alpha; Pulmozyme;