primary studies - published RCT

Two years experience with recombinant human DNase I in the treatment of pulmonary disease in cystic fibrosis.

Code: PM7480980 **Year:** 1995 **Date:** 1995 **Author:** Shah PL

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

open label study

Participants

A cohort of 52 cystic fibrosis patients with a FVC > 40% predicted were enrolled. 26 male and 26 female patients with a mean FVC of 2.941 and FEV1 of 1.471 were recruited. Thirteen patients did not complete the study; there were seven deaths, three patients withdrew consent and three patients were lost to follow-up.

Interventions

They received 2.5 mg rhDNase twice daily for 6 months followed by a 2-week wash-out period, and for the subsequent 18 months were treated with rhDNase once daily.

Outcome measures

Ipulmonary function

Main results

Improvement in pulmonary function was seen following treatment and changes were evaluated as mean percent change from baseline. The maximum improvement occurred in the first month followed by a plateau at a lower level of improvement. The mean improvement in FEV1 over the first month was 13.3% (range 12-14.1%), followed by a plateau at around 7.1% (range 4.6-11.0%) for the subsequent 23 months. Mean FVC was improved by 12.03% (range 9.0-14.3%) over the first month and subsequently 4.2% (range - 2.2-10.2%). The effects on pulmonary function were similar for both treatment doses of rhDNase. There was also a steady improvement in weight from a mean of 54.2 kg to 55.7 kg at the end of the study.

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See also

Respiratory medicine YR: 1995 VL: 89 NO: 7

Keywords

Adolescent; Adult; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; pharmacological_intervention; Recombinant Proteins; Respiratory System Agents; Dornase alpha; Pulmozyme; Inhalation OR nebulised; nebuliser;