*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;