*primary studies - published RCT*

# Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in patients with cystic fibrosis. The Pulmozyme Study Group.

**Code:** PM7503821 **Year:** 1994 **Date:** 1994 **Author:** Fuchs HJ

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

Randomised, double-blind parallel trial with 3 arms over 24 weeks.

### Participants

968 participants, diagnosed CF on genotype, sweat test or clinically, aged over five years with FVC > 40 % predicted and clinically stable. 25 people withdrew from the study, 8 in the placebo group and once-daily group and 9 in the twice-daily group.

### Interventions

Nebulized dornase alfa 2.5 mg od (n = 322) or bd (n = 321) compared to placebo (n = 325), over 24 weeks. QoL questionnaire

### Outcome measures

Outcomes included in this review: pulmonary-function tests, dyspnea, patients' general well-being and cystic fibrosis-related symptoms, number of days of school or work missed, number of days in the hospital, number of days patients received parenteral antibiotics, serum rhDNase antibodies and serum concentration of DNase

### Main results

One or more exacerbations occurred in 27 percent of the patients given placebo, 22 percent of those treated with rhDNase once daily, and 19 percent of those treated with rhDNase twice daily. As compared with placebo, the administration of rhDNase once daily and twice daily reduced the age-adjusted risk of respiratory exacerbations by 28 percent (P = 0.04) and 37 percent (P

### Authors' conclusions

In patients with cystic fibrosis, the administration of rhDNase reduced but did not eliminate exacerbations of respiratory symptoms, resulted in slight improvement in pulmonary function, and was well tolerated.

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### See also

N Engl J Med. 1994 Sep 8;331(10):637-42.

### Keywords

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