primary studies - published RCT

Multicentric trial of rhDNase in patients with cystic fibrosis and severe pulmonary dysfunction.

Code: PM7663660 **Year:** 1995 **Date:** 1995 **Author:** Hodson M

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

randomized, double-blind, placebo- controlled, multicenter study. After the completion of the randomized study, there was an open-label phase

Participants

The first three aerosolisations were performed in the hospital, after bronchial drainage. 70 patients with cystic fibrosis and severe impairment of pulmonary function, aged 5 to 48 years

Interventions

RCT: aerosolised rhDNase 2.5 mg twice daily for 2 weeks (three aerosolisations were performed in the hospital, after bronchial drainage). Open- label phase for 6 months: all patients received rhDNase.

Outcome measures

Respiratory parameters

Main results

Respiratory parameters improved in both groups during the study period. As compared to baseline values, FVC improved by 13.7% and 12.7%, forced expiratory volume in one second (FEV1) by 6% and 7%, respectively in the placebo and rh DNase groups. No significant difference was detected between the two groups. In the open- label phase FEV1 and FVC further improved in all patients.

Authors' conclusions

We failed to demonstrate for severely ill patients with cystic fibrosis a significant advantage for aerosolised rhDNase compared to placebo for two weeks. The further improvement observed in the open-label phase suggests that more prolonged treatment might be necessary to detect a statistically significant benefit. No significant side effects of the treatment were observed.

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See also

Arch Pediatr. 1995 Jul;2(7):679-81.

Keywords

Adolescent; Adult; Child; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; pharmacological_intervention; placebo; Respiratory System Agents; Respiratory Tract Diseases; Dornase alpha; Pulmozyme;