primary studies - published RCT

In vivo effects of recombinant human DNase I on sputum in patients with cystic fibrosis.

Code: PM8711640 **Year:** 1996 **Date:** 1996 **Author:** Shah PL

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

RCT

Participants

Patients with cystic fibrosis

Interventions

Patients were randomised to receive either placebo or rhDNase 2.5 mg twice daily for 10 days.

Outcome measures

Sputum samples were collected in sterile containers during screening and during treatment with the study drug. Pulmonary function and rheological analysis were the primary outcomes evaluated. Other parameters assessed were quantitative sputum bacteriology, sputum DNA concentration, and change in molecular mass of DNA polymers.

Main results

The viscoelasticity of the sputum in untreated patients with cystic fibrosis was high and treatment with rhDNase reduced all the rheological parameters measured: dynamic storage modulus (a measure of elasticity), dynamic loss modulus (a measure of viscosity), and log complex modulus (a measure of mucus rigidity). The calculated cough clearance index was also improved following treatment with rhDNase. These rheological parameters showed a correlation with forced expiratory volume in one second (FEV1) which was improved by a mean (SE) of 13.3 (5.6)% on day 10 of treatment with rhDNase compared with a change of 0.2 (3.1)% in the placebo group. There was no change in bacterial colony counts or sputum DNA concentrations following treatment with rhDNase, but a small decrease in high molecular weight DNA was observed.

Authors' conclusions

Patients with cystic fibrosis treated with rhDNase show an improvement in rheological properties and pulmonary function, one of the mechanisms being a reduction in the proportion of high molecular weight DNA.

http://dx.doi.org/10.1136/thx.51.2.119

See also

Thorax. 1996 Feb;51(2):119-25.

Keywords

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