primary studies - published RCT

Recombinant human DNase I in cystic fibrosis patients with severe pulmonary disease: a short-term, double-blind study followed by six months open-label treatment.

Code: PM7589382 **Year:** 1995 **Date:** 1995 **Author:** Shah PI

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

double-blind, randomized, placebo-controlled trial

Participants

70 most severly ill CF patients (FVC

Interventions

2.5 mg rhDNase twice daily or placebo for a period of 14 days followed by a 6 month open extension period (OEP). During the OEP, all patients received 2.5 mg rhDNase twice daily.

Outcome measures

safety and efficacy of rhDNase

Main results

In both the double-blind period and the OEP the drug appeared to be safe. During the double-blind study, forced expiratory volume in one second (FEV1) and FVC improved in both groups but there was no statistically significant difference between the groups. In the OEP, there was mean improvement in percentage predicted FEV1 and FVC, 9 and 18%, respectively, for all patients participating.

Authors' conclusions

In conclusion, DNase is safe when administered in conjunction with a rigorous regimen of chest physiotherapy to severely ill patients (FVC

http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/095/CN-00120095/frame.html

See also

Eur Respir J. 1995 Jun;8(6):954-8.

Keywords

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