primary studies - published RCT

Aerosolized recombinant human DNase in hospitalized cystic fibrosis patients with acute pulmonary exacerbations.

Code: PM8665055 **Year:** 1996 **Date:** 1996 **Author:** Wilmott RW

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

Randomised double-blind parallel designed trial

Participants

80 participants, aged over 5 years admitted to hospital for at least 1 night for treatment of a chest exacerbation (protocol defined) with FVC > 35% predicted. CF was diagnosed on genotype, sweat test. No withdrawals mentioned in the paper.

Interventions

Comparison of dornase alfa 2.5 mg bd (n = 43) nebulised with placebo (n = 37) over 15 days.

Outcome measures

Measurements taken on days 1, 8 and 15. Mean change in % predicted FVC and FEV1, number of deaths and number experiencing an adverse event, quality of life score and dyspnoea score.

Main results

Administration of rhDNase was not associated with acute adverse events or deaths, and no patients experienced allergic or anaphylactic reactions. Although forced expiratory volume in one second (FEV1) and FVC improved in both treatment groups during the double-blind period, there were no statistically significant differences in the mean change from baseline in FEV1 or FVC between the two groups.

Authors' conclusions

rhDNase therapy is safe and well tolerated in CF patients with acute exacerbations requiring hospitalization, but the study did not demonstrate a statistically significant therapeutic effect of rhDNase when added to a regimen of antibiotics and chest physical therapy.

http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/584/CN-00126584/frame.html

See also

Am J Respir Crit Care Med. 1996 Jun;153(6 Pt 1):1914-7.

Keywords

Adult; Combined Modality Therapy; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Hospitalization; Hospital care; Inhalation OR nebulised; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Recombinant Proteins; Exacerbation; Respiratory Tract Infections; Infection; Bacterial Infections; Respiratory System Agents; Chest physiotherapy; Respiratory Tract Diseases; Dornase alpha; Pulmozyme;