primary studies - published RCT

Efficacy and safety of short-term administration of aerosolised recombinant human DNase I in adults with stable stage cystic fibrosis.

Code: PM8100928 **Year:** 1993 **Date:** 1993 **Author:** Ranasinha C

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

Randomised, double-blind, parallel design safety and efficacy trial over 10 days with follow up to 42 days.

Participants

71 adults with CF diagnosed by genotype, sweat test. All participants had stable disease and FVC > 40% predicted.

Interventions

Comparison of nebulized dornase alfa 2.5 mg bd (n = 36) with placebo (n = 35), given for 10 days.

Outcome measures

Included in this review: mean change in % predicted FVC and FEV1; number of deaths; and number experiencing an adverse event. Not included in this review: mean number of days AB used as only recorded at end of 42 day follow-up period. Measurements taken at days 3, 6 and 10.

Main results

All 71 randomised patients, aged 16-55, completed every aspect of the study and baseline characteristics were similar in the two groups. Baseline forced expiratory volume in one second (FEV1) was 46% of predicted for patients randomised to rhDNase, and 48% for those randomised to placebo; and baseline FVC was 76% of predicted for both groups. The mean percentage change in FEV1 from baseline was a 13.3% rise on rhDNase and a 0.2% fall on placebo (p

Authors' conclusions

This study confirms that short-term administration of rhDNase in stable patients with cystic fibrosis is safe and improves lung function.

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See also

Lancet. 1993 Jul 24;342(8865):199-202.

Keywords

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