primary studies - published RCT

Effects of 12-week administration of dornase alfa in patients with advanced cystic fibrosis lung disease. Pulmozyme Study Group.

Code: PM8874241 **Year:** 1996 **Date:** 1996 **Author:** McCoy K

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

Randomised, double-blind, parallel design trial over 12 weeks.

Participants

40 participants withdrew from the trial, five due to adverse events, 10 withdrew consent, 1 did not comply with the study protocol, 15 died, 2 were unavailable for follow up and 7 stopped for a medical procedure. 320 participants with CF diagnosed clinically, by genotype or sweat test. Participants aged from 7 to 57 years, with FVC

Interventions

Comparison of nebulized dornase alfa 2.5 mg od (n = 158) to placebo (n = 162) over 12 weeks.

Outcome measures

Measurements were taken on days 8, 15, 29, 57 and 85. Included in this review: mean change in % predicted FVC and FEV1, number of deaths and number experiencing adverse event, relative risk of one or more respiratory exacerbation.

Main results

Dornase alfa improved the mean percent change in FEV1 from baseline by 9.4% compared with 2.1% for placebo (p

Authors' conclusions

Pulmonary function as measured by FEV1 and FVC improved significantly in the dornase alfa-treated patients. Dornase alfa was found to be safe and well tolerated over the 12-week study period.

http://dx.doi.org/10.1378/chest.110.4.889

See also

Chest. 1996 Oct;110(4):889-95.

Keywords

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