

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;