

primary studies - published RCT

Bronchodilatory effects of salbutamol, ipratropium bromide, and their combination: double-blind, placebo-controlled crossover study in cystic fibrosis.

Code: PM11389575 **Year:** 2001 **Date:** 2004

Author: Ziebach R

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

two-year randomized double-blind placebo-controlled study

Participants

6 CF children (6-11 years) received treatment; 8 CF patients received placebo

Interventions

recombinant human DNase I (dornase alpha) or placebo

Outcome measures

exhaled NO (FENO) and pulmonary function

Main results

Mean age at enrollment was 8 years (range 6 to 11 years), mean forced vital capacity (FVC) was 112% (range 86 to 133%), and mean forced expiratory volume in one second (FEV1) was 109% (range 88 to 128%) of predicted values. In five of six (83%) of the dornase alpha treated patients, FENO changed in parallel to changes in pulmonary function tests while no such correlation was observed in any of the eight patients receiving placebo. This difference between treatment groups was statistically significant for both FVC ($P = 0.026$, Wilcoxon-test) and FEV1 ($P = 0.042$).

Authors' conclusions

These data suggest that FENO may serve as a surrogate measure for evaluating the effectiveness of interventions that affect airway clearance in CF.

<http://dx.doi.org/10.1002/ppul.1071>

See also

Pediatr Pulmonol. 2001 Jun;31(6):431-5.

Keywords

Child; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; placebo; Recombinant Proteins; Respiratory System Agents; Dornase alpha; Pulmozyme;