primary studies - published RCT

Long-term comparative trial of positive expiratory pressure versus oscillating positive expiratory pressure (flutter) physiotherapy in the treatment of cystic fibrosis.

Code: PM11391327 **Year:** 2001 **Date:** 2005 **Author:** McIlwaine PM

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

1-year, double-blind, placebo-controlled trial

Participants

25 children with mild cystic fibrosis (CF) lung disease

Interventions

daily rhDNase or placebo aerosol

Outcome measures

HRCT and spirometry were evaluated at baseline, and at 3 months and 12 months. Outcome variables were percentage of predicted FVC, FEV1, and forced expiratory flow, midexpiratory phase (FEF(25-75%)); total and subcomponent visual HRCT scores; and quantitative air trapping measurements derived from chest HRCT images

Main results

At baseline, there were no statistical differences between groups in any of the variables used as an outcome. After 3 months of treatment, both groups had improvements in percentage of predicted FEV1 and FEF(25-75%), and total HRCT visual scores. In contrast, the rhDNase group had a 13% decrease in quantitative air trapping from baseline (severe air trapping [A3]), compared to an increase of 48% in the placebo group ($p = 0.023$). After 12 months, both groups had declines in percentage of predicted FVC and FEV1, but the rhDNase group retained improvements in percentage of predicted FEF(25-75%) and quantitative air trapping. The mucus plugging and total HRCT visual scores were also improved in the rhDNase group after 12 months of treatment, with and without significant differences between groups ($p = 0.026$ and $p = 0.676$). Quantitative air trapping (A3) remained improved in the rhDNase group (- 15.4%) and worsened in the placebo group (+61.3%) with nearly significant differences noted between groups ($p = 0.053$) after 12 months of treatment.

Authors' conclusions

Quantitative air trapping is a more consistent sensitive outcome measure than either spirometry or total HRCT scores, and can discriminate differences in treatment effects in children with minimal CF lung disease.

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See also

J Pediatr. 2001 Jun;138(6):845-50.

Keywords

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