primary studies - published RCT

A crossover, randomized, controlled trial of dornase alfa before versus after physiotherapy in cystic fibrosis.

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

crossover, randomized, double-blind, and placebo-controlled trial.

Participants

52 patients who had CF (27 female) with mild to moderate suppurative lung disease, were a mean +/- SD age of 10.7 +/- 3.2 years, had Shwachman scores of 86 +/- 11.8, had predicted FEV1 of 83% +/- 18%, had quality of well-being score of 0.76 +/- 0.08, and had VO2max of 42.6 +/- 6.3 ml/kg per min were enrolled. 50 patients completed the study.

Interventions

2 treatment orders. Dornase alfa before + placebo after physiotherapy/PEP for 2 weeks was followed by a 2-week washout and then the reverse order placebo before and dornase alfa after physiotherapy/PEP for the final 2 weeks. The second treatment order reversed the placebo and dornase alfa therapy for the first and last 2-week blocks.

Outcome measures

The main outcome measures used included the change in predicted percentage of forced expiratory volume in 1 second (FEV1), a composite quality of well-being score (QWB), and a measure of aerobic fitness (maximal oxygen consumption, [VO2max]), determined using shuttle testing.

Main results

Nonsignificant mean (95% confidence interval) differences in FEV1 (0.02 L [-0.05 to 0.10]), VO2max (-0.75 ml/kg per min [-1.85 to 0.35]), and QWB (0.005 [-0.94 to 0.0028]) for dornase alfa after physiotherapy/PEP were detected. A post hoc analysis showed that patients who were colonized persistently with Pseudomonas aeruginosa had a significantly greater improvement in FEV1 (0.12 L [0.23 to 0.01] vs -0.04 L [0.05 to -0.13]) when dornase alfa was administered after physiotherapy/PEP.

Authors' conclusions

Dornase alfa is equally efficacious when delivered before or after physiotherapy/PEP in patients with CF. Patients who are colonized persistently with P aeruginosa may derive more improvement in FEV1 when dornase alfa is delivered after physiotherapy/PEP.

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See also

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Keywords

Adolescent; Bacterial Infections; Child; Deoxyribonuclease; Drug Administration Schedule; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Infection; Inhalation OR nebulised; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Recombinant Proteins; Respiratory Tract Infections; Respiratory System Agents; Respiratory Tract Diseases; Dornase alpha; Pulmozyme;