

primary studies - published RCT

## **A phase 2 study of aztreonam lysine for inhalation to treat patients with cystic fibrosis and Pseudomonas aeruginosa infection.**

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

A randomised crossover trial with concealed allocation, intention-to-treat analysis and blinding of patients, therapists, and assessors

### **Participants**

Twenty adults with cystic fibrosis who were not taking dornase alpha were recruited, of whom 17 were randomised and completed the trial.

### **Interventions**

Participants performed an individually tailored session of physical airway clearance techniques for at least 15 minutes per day for 28 days. For 14 days, dornase alpha was inhaled before each session of airway clearance techniques and a placebo was inhaled after. For the other 14 days, placebo was inhaled before and dornase alpha after airway clearance techniques. The order of the two 14-day periods was randomised.

### **Outcome measures**

The primary outcome was the forced expiratory volume in 1 sec (FEV(1)). Secondary outcomes were forced vital capacity, 24-hour sputum production, sputum production during the airway clearance regimen, oxygen saturation, peak oxygen consumption during an incremental exercise test, oxygen desaturation during exercise, and quality of life.

### **Main results**

Inhalation of dornase alpha after airway clearance techniques did not significantly affect the change in FEV(1) compared with inhalation before airway clearance techniques, mean difference 0.04 L, 95% CI -0.14 to 0.23. None of the secondary outcomes differed significantly between the study arms. There was good correlation between the change in FEV(1) and the change in quality of life scores.

### **Authors' conclusions**

Timing of dornase alpha can be selected according to convenience, patient preference, or to accommodate the timing of other medications in the treatment regimen.

<http://dx.doi.org/10.1002/ppul.20736>

### **See also**

Pediatr Pulmonol. 2008 Jan;43(1):47-58.

### **Keywords**

Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; pharmacological\_intervention; Respiratory System Agents; Airway clearance technique; Chest physiotherapy; non pharmacological intervention - devices OR physiotherapy; Inhalation OR nebulised; nebuliser; Dornase alpha; Pulmozyme;