

primary studies - published RCT

## **Recombinant human DNase I in cystic fibrosis patients with severe pulmonary disease: a short-term, double-blind study followed by six months open-label treatment.**

**Code:** PM7589382

**Year:** 1995 **Date:** 1999

**Author:** Shah PI

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

Cross-over design. Randomised trial.

### **Participants**

15 participants (gender unspecified); age range 5 - 17 years. Participants were excluded if they had a hospital admission during the month prior to the start of the study or were clinically unstable (based on respiratory rate, heart rate, oxygen saturation, breath sounds, sputum production and medication use). CF defined by mild-mod Schwachman score and a productive cough.

### **Interventions**

1. PEP treatment. Participants breathed through a Vital Signs 9000 mask; 2. Postural drainage and chest physiotherapy (CPT). Not defined; 3. Oscillating PEP (Flutter). Participants breathed through a Scandipharm Flutter device. Not further defined. Each therapy was performed for 15 minutes, 3 times a day, for 1 month. Chest physiotherapy and postural drainage was used between the therapies to return each of the participants to his or her baseline status.

### **Outcome measures**

FEV1, FEF25-75, and oxygen saturation were measured at the beginning and end of each intervention period.

### **Main results**

No respiratory assessment parameters changed between the therapies studied. All patients who used the Flutter preferred it over the other two therapies. The patients stated they felt better clinically, were able to expectorate mucus more easily, and felt more in control of their therapies. Paired t-test statistical analysis from the PFT data indicated no significant changes in forced expiratory volume in the first second of expiration (FEV1), forced expiratory flow from 25 percent to 75 percent of the loop (FEF25-75), airway resistance (Raw), or specific airway conductance (sGaw) among the three therapies studied.

### **Authors' conclusions**

This study has shown no significant change in respiratory assessment parameters or pulmonary function. Further studies involving multicenter trials are warranted to evaluate the effects of the Flutter on pulmonary function.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/095/CN-00120095/frame.html>

### **See also**

Eur Respir J. 1995 Jun;8(6):954-8.

### **Keywords**

Adolescent; Airway clearance technique; Child; Drainage; flutter; non pharmacological intervention - devices OR physiotherapy; pharmacological\_intervention; Postural Drainage; Vibration; oscillating devices; Chest physiotherapy;