

primary studies - published RCT

## **Ursodeoxycholic acid improves the hepatic metabolism of essential fatty acids and retinol in children with cystic fibrosis.**

**Code:** PM9003851

**Year:** 1997 **Date:** 2001

**Author:** Lepage G

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

Parallel design. Treatment for 1 year. Randomised trial.

### **Participants**

40 participants (24 male); age range 7 - 17 years; FEV1 range 47 - 107% predicted; Schwachman score range 54 - 98 points. Participants were excluded if they had been hospitalised within the past month for a pulmonary exacerbation, or if they were not stable. CF confirmed by sweat test.

### **Interventions**

1. PEP treatment. Participants inhaled and exhaled through the Astra Meditec PEP mask in sitting. The resistor which produced 10 to 20 cm H<sub>2</sub>O pressure during mid-expiration was used. Over approximately 2 minutes, 15 tidal breaths with slightly active expir 2. Oscillating PEP. Participants exhaled through the Flutter device (Flutter). The device was angled to maximise the sensation of vibration in the chest. In sitting, subjects inhaled deeply through the nose, followed by a breath hold for 2 - 3 seconds, an The daily regimen for use of the devices is not described.

### **Outcome measures**

FEV1, FVC, and FEF25-75 were measured at the beginning and at three-monthly intervals throughout the study. Compliance with the interventions was recorded daily by the participants. A monthly questionnaire recorded physical activity, general well-being

### **Main results**

The flutter group demonstrated a greater mean annual rate of decline in forced vital capacity compared with the PEP group (-8.62 +/- 15.5 vs 0.06 +/- 7.9; P =.05) with a similar trend in forced expiratory volume in 1 second (-10.95 +/- 19.96 vs -1.24 +/- 9.9; P =.08). There was a significant decline in Huang scores (P =.05), increased hospitalizations (18 vs 5; P =.03), and antibiotic use in the flutter group.

### **Authors' conclusions**

Flutter was not as effective in maintaining pulmonary function in this group of patients with CF compared with PEP and was more costly because of the increased number of hospitalizations and antibiotic use.

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### **See also**

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### **Keywords**

Adolescent; Airway clearance technique; Child; flutter; non pharmacological intervention - devices OR physiotherapy; Chest Wall Oscillation; Positive-Pressure Respiration- PEP- pep mask; Inhalation OR nebulised; oscillating devices; Chest physiotherapy;