primary studies - published RCT

Lessons learned from a randomized trial of airway secretion clearance techniques in cystic fibrosis.

Code: PM20146387 **Year:** 2010 **Date:** 2010 **Author:** Sontag MK

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

RCT. 20 centres. Electronic randomisation, stratified by age

Participants

166 individuals, aged 7 years or older, CF confirmed by sweat chloride or genotype.

Interventions

PD, flutter device (FD) and vest.

Outcome measures

change in pulmonary function, time to need for intravenous (IV) antibiotics, use of pulmonary therapies, adherence to treatment, treatment satisfaction, and quality of life. Clinical outcomes were assessed quarterly over 3 years

Main results

Enrollment goals were not met, and withdrawal rates were high, especially in postural drainage (51%) and FD (26%), compared to vest (9%), resulting in early termination. FEV(1) decline, time to need IV antibiotics, and other pulmonary therapies were not different. The annual FEF(25-75%) predicted rate of decline was greater in those using vest (P = 0.02). Adherence was not significantly different (P = 0.09). Overall treatment satisfaction was higher in vest and FD than in postural drainage (P

Authors' conclusions

The study was ended early due to dropout and smaller than expected decline in FEV(1). Patients were more satisfied with vest and FD. The longitudinal decline in FEF(25-75%) was faster in vest; we found no other difference in lung function decline, taken together this warrants further study. The slow decline in FEV(1) illustrates the difficulty with FEV(1) decline as a clinical trial outcome.

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See also

Pediatr Pulmonol. 2010 Mar;45(3):291-300.

Keywords

Adolescent; Adult; Airway clearance technique; Chest Wall Oscillation; Child; Drainage; non pharmacological intervention - devices OR physiotherapy; Postural Drainage; flutter; oscillating devices; Chest physiotherapy;