primary studies - published RCT

Assessing the usefulness of outcomes measured in a cystic fibrosis treatment trial.

Code: PM16806875 **Year:** 2007 **Date:** 2007 **Author:** Suri R

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

The study was performed as part of a trial comparing daily rhDNase with alternate day rhDNase and hypertonic saline in CF.

Interventions

daily rhDNase with alternate day rhDNase and hypertonic saline

Outcome measures

The primary outcome was FEV(1). Secondary outcomes were forced vital capacity (FVC), forced expiratory flow at 25-75% of forced vital capacity (FEF(25-75)), number of pulmonary exacerbations, weight gain, quality of life (QOL), and exercise tolerance. The usefulness of each secondary outcome was investigated by assessing if the change in that outcome over the treatment period could be predicted from the primary outcome

Main results

Change in FEV(1) correlated with changes in FVC (r(2)=0.76, P=0.001), FEF(25-75) (r(2)=0.64, P=0.001), weight (r(2)=0.08, P=0.001), and change in oxygen saturation with exercise (r(2)=0.08, P=0.001). However, it did not correlate with changes in visual analogue score (VAS) with exercise, QOL, nor with the occurrence of pulmonary exacerbations.

Authors' conclusions

Only the outcomes QOL and VAS with exercise actually provided additional information to FEV(1) in this study.

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See also

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Keywords

Child; Deoxyribonuclease; Drug Administration Schedule; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Infection; pharmacological_intervention; Respiratory Tract Infections; Respiratory System Agents; Respiratory Tract Diseases; Dornase alpha; Pulmozyme; Inhalation OR nebulised; nebuliser;