primary studies - published RCT

Composite spirometric-computed tomography outcome measure in early cystic fibrosis lung disease.

Code: PM12746252 **Year:** 2003 **Date:** 2003 **Author:** Robinson TE

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

1-year RCT

Participants

25 CF children

Interventions

daily Pulmozyme or normal saline aerosol

Outcome measures

Outcome variables were pulmonary function test (PFT) results, a global HRCT score, and a composite score incorporating PFTs and HRCT scoring. Regression analyses with generalized estimating equations permitted estimation of the difference in treatment effect between groups over time for each outcome.

Main results

The largest difference in treatment effects observed at 12 months, measured by the percentage change from baseline, were with the composite total and maximal CT/PFT scores (35.4 and 30.4%), compared with mean forced expiratory flow during the middle half of the FVC (FEF25-75%) (13.0%) and total and maximal global HRCT scores (6.2%, 7.2%).

Authors' conclusions

The composite total and maximal CT/PFT scores were the most sensitive outcome measures for discriminating a treatment effect in children with cystic fibrosis with normal or mildly reduced pulmonary function during a 1-year trial of Pulmozyme.

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See also

Am J Respir Crit Care Med. 2003 Sep 1;168(5):588-93. Epub 2003 May 13.

Keywords

Adolescent; Child; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; pharmacological_intervention; computed tomography; diagnostic procedures; non pharmacological intervention - diagn; Respiratory System Agents; Dornase alpha; Pulmozyme; Inhalation OR nebulised; nebuliser;