

primary studies - published RCT

Aerosolized recombinant human DNase in hospitalized cystic fibrosis patients with acute pulmonary exacerbations.

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

RCT, cross-over design

Participants

13 patients completed the study. Patients' age ranged between 18-38 years, and they had baseline values of FEV(1) of 27-103% of predicted values.

Interventions

Following the measurement of baseline clearance, patients were given a 7-day course of either rhDNase or placebo. The patient then returned on the seventh day for follow-up clearance measurements. This was followed by a 2-week washout period before the whole process was repeated with the alternative inhalation solution.

Outcome measures

On each of the study days, mucociliary clearance was initially measured for a period of 60 min (IC). This was followed by cough clearance (CC) measurements for 30 min, during which patients were requested to cough a total of 120 times. Post-cough clearance (PCC) was then measured for a further 60 min.

Main results

Following completion of the course of rhDNase, there was a mean percent increase from baseline of 7.5% for FEV(1) and 5.4% for FVC% (P = 0.03). There was a small, nonsignificant increase in IC (6.2 +/- 3.6%) on the rhDNase arm compared with the placebo arm (-2.3 +/- 2.9%), P = 0.1. No changes were seen in either CC (1.0 +/- 3.2% [rhDNase] vs. 1.9 +/- 2.4% [placebo], P = 0.9) or PCC (-0.7 +/- 1.5% [rhDNase] vs. 0.9 +/- 1.7% [placebo], P = 0.3). Patients who achieved a 10% or greater improvement in FEV(1) (n = 5) in response to rhDNase did not show any greater change in clearance than nonresponders.

Authors' conclusions

Any improvements in either ciliary or cough clearance in response to a short course of rhDNase was not demonstrated. The mechanism of action of this drug in vivo remains uncertain.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/584/CN-00126584/frame.html>

See also

Am J Respir Crit Care Med. 1996 Jun;153(6 Pt 1):1914-7.

Keywords

Adolescent; Adult; Deoxyribonuclease; Inhalation OR nebulised; pharmacological_intervention; Recombinant Proteins; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents; Dornase alpha; Pulmozyme;