primary studies - published RCT

In vivo effects of recombinant human DNase I on sputum in patients with cystic fibrosis.

Code: PM8711640 **Year:** 1996 **Date:** 2000 **Author:** Shah PL

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

Parallel design. RCT.

Participants

Multi-centre. 70 males, 67 females; mean (SD) age 11.5 (4.0) years; range 5.3 - 24.6 years. 137 participants with CF. CF diagnosed with 2 sweat tests with chloride >60 meq/L. Inclusion criteria: older than 5 years; able to do spirometry; FVC >50%; FEV1 % >50%; FEF 25-75 30% of predicted values; no antibiotics for URTI for a week prior to inclusion.

Interventions

Control group: nebulised saline 5ml, 3x daily for 6 months. Treatment group: nebulised amiloride 1.5 mg/5 ml saline(10-3 mol/L), 3x daily for 6 months.

Outcome measures

FEV1; FVC; relative change; need for extra treatment; nutritional parameters; respiratory exacerbations; acquisition of respiratory pathogens.

Main results

The present study failed to demonstrate any significant benefit of amiloride over placebo on FVC, FEV(1), and the other secondary endpoints in the studied population. Neither the chronically colonized, nor the noncolonized patients benefited. The confidence intervals of the differences between treatment groups indicated small differences that were most likely of no clinical significance. Complementary analyses taking into account the gender, the type of mutation, the subpopulations whose FVC and FEV(1) were below 80% of normal values at the beginning of the study, and also patients less than 10 years old, did not show any statistically or clinically significant improvements following amiloride therapy.

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See also

Thorax. 1996 Feb;51(2):119-25.

Keywords

Adolescent; Adult; Amiloride; Child; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; placebo; Airway clearance drugs -expectorants- mucolytic- mucociliary-; colonization; Infection; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Infections; ENaC antagonists - Sodium Channel Blockers; Respiratory System Agents; Respiratory Tract Diseases;