primary studies - published RCT

A controlled trial of long-term inhaled hypertonic saline in patients with cystic fibrosis.

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

double-blind, parallel-group randomized trial

Participants

164 patients with stable cystic fibrosis who were at least six years old

Interventions

inhale 4 ml of either 7 percent hypertonic saline or 0.9 percent (control) saline twice daily for 48 weeks, with quinine sulfate (0.25 mg per milliliter) added to each solution to mask the taste. A bronchodilator was given before each dose, and other standard therapies were continued during the trial.

Outcome measures

slope in lung function (reflected by the forced vital capacity [FVC], forced expiratory volume in one second [FEV1], and forced expiratory flow at 25 to 75 percent of FVC [FEF25-75], n° of pulmonary exacerbations, bacterial infection and inflammation

Main results

The rate of change (slope) in lung function during the 48 weeks of treatment, did not differ significantly between groups (P=0.79). However, the absolute difference in lung function between groups was significant (P=0.03) when averaged across all post-randomization visits in the 48-week treatment period. As compared with the control group, the hypertonic-saline group had significantly higher FVC (by 82 ml; 95 percent confidence interval, 12 to 153) and FEV1 (by 68 ml; 95 percent confidence interval, 3 to 132) values, but similar FEF25-75 values. The hypertonic-saline group also had significantly fewer pulmonary exacerbations (relative reduction, 56 percent; P=0.02) and a significantly higher percentage of patients without exacerbations (76 percent, as compared with 62 percent in the control group; P=0.03). Hypertonic saline was not associated with worsening bacterial infection or inflammation.

Authors' conclusions

Hypertonic saline preceded by a bronchodilator is an inexpensive, safe, and effective additional therapy for patients with cystic fibrosis.

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See also

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Keywords

Adolescent; Adult; Albuterol; Anti-Bacterial Agents; Child; Combined Modality Therapy; hydration; Hypertonic Solutions; Inhalation OR nebulised; Isotonic Solutions; pharmacological_intervention; Sodium Chloride; Adrenergic beta-Agonists; Respiratory System Agents;