primary studies - published RCT

Inhaled Hypertonic Saline in Infants and Children Younger Than 6 Years With Cystic Fibrosis: The ISIS Randomized Controlled Trial.

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

Infant Study of Inhaled Saline in Cystic Fibrosis (ISIS): a multicenter, randomized, double-blind, placebo-controlled trial

Participants

Children aged 4 to 60 months with an established diagnosis of CF from 30 CF care centers in the United States and Canada. A total of 344 patients were assessed for eligibility; 321 participants were randomized; 29 (9%) withdrew prematurely.

Interventions

The active treatment group (n = 158) received 7% hypertonic saline and the control group (n = 163) received 0.9% isotonic saline, nebulized twice daily for 48 weeks. Both groups received albuterol or levalbuterol prior to each study drug dose.

Outcome measures

Rate during the 48-week treatment period of protocol-defined pulmonary exacerbations treated with oral, inhaled, or intravenous antibiotics.

Main results

The mean pulmonary exacerbation rate (events per person-year) was 2.3 (95% CI, 2.0-2.5) in the active treatment group and 2.3 (95% CI, 2.1-2.6) in the control group; the adjusted rate ratio was 0.98 (95% CI, 0.84-1.15). Among participants with pulmonary exacerbations, the mean number of total antibiotic treatment days for a pulmonary exacerbation was 60 (95% CI, 49-70) in the active treatment group and 52 (95% CI, 43-61) in the control group. There was no significant difference in secondary end points including height, weight, respiratory rate, oxygen saturation, cough, or respiratory symptom scores. Infant pulmonary function testing performed as an exploratory outcome in a subgroup (n = 73, with acceptable measurements at 2 visits in 45 participants) did not demonstrate significant differences between groups except for the mean change in forced expiratory volume in 0.5 seconds, which was 38 mL (95% CI, 1-76) greater in the active treatment group. Adherence determined by returned study drug ampoules was at least 75% in each group. Adverse event profiles were also similar, with the most common adverse event of moderate or severe severity in each group being cough (39% of active treatment group, 38% of control group).

Authors' conclusions

Among infants and children younger than 6 years with cystic fibrosis, the use of inhaled hypertonic saline compared with isotonic saline did not reduce the rate of pulmonary exacerbations over the course of 48 weeks of treatment.

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See also

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Keywords

Child; hydration; Hypertonic Solutions; pharmacological_intervention; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents;