primary studies - published RCT

Inhaled hypertonic saline in infants and toddlers with cystic fibrosis: short-term tolerability, adherence, and safety.

Code: PM21365779 **Year:** 2011 **Date:** 2011 **Author:** Rosenfeld M

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

Three-center, open label evaluation

Participants

children with CF 12-30 months of age.

Interventions

7% HS administered twice daily for 14 days

Outcome measures

short-term tolerability, adherence, and safety

Main results

Twenty children were enrolled. One was withdrawn due to maternal concern over fussiness with application of the facemask for the test dose. Of the 19 participants administered the test dose, 1 was withdrawn due to test dose intolerance (5%, 95% confidence interval 0, 26%). Eighteen participants completed the study; 1 was intolerant (95% CI 0, 27%) at the final visit due to new wheezes on exam in association with an upper respiratory infection and otitis media. Home symptom diaries demonstrated cough as the main symptom in the hour following inhalation, which decreased in frequency over the study period. Adherence as assessed by daily home diary and returned study drug ampoules was high. Participants reported receiving both treatments on a median of 100% of days; a median of 25 ampoules were used during a median of 13 days.

Authors' conclusions

7% HS appears well tolerated for up to 14 days in infants and toddlers with CF, with high adherence. These results provide encouraging short-term tolerability and adherence data for future trials assessing the safety and efficacy of 7% HS in young children with CF.

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See also

Pediatr Pulmonol. 2011 Jul;46(7):666-71

Keywords

Hypertonic Solutions; Respiratory System Agents; pharmacological_intervention; Inhalation OR nebulised;