primary studies - published RCT

Inhaled dry powder mannitol in children with cystic fibrosis: A randomised efficacy and safety trial.

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

Phase 2, randomised, placebo-controlled crossover study.

Participants

Children with cystic fibrosis (CF) aged 6-17years.

Interventions

Subjects were randomly assigned to mannitol 400mg every 12h or matching placebo for 8weeks, followed by an 8week washout and an 8week period with the alternate treatment.

Outcome measures

The primary endpoint was the absolute change from baseline in ppFEV1 (percent predicted FEV1).

Main results

A total of 92 subjects were studied, with a mean age of 12years and mean baseline ppFEV1 of 72.2%. During mannitol treatment ppFEV1 was 3.42% (p=0.004) higher compared to placebo or a 4.97% (p=0.005) relative difference; relative change from baseline FEF25-75 was 10.52% (p=0.013). During mannitol treatment, acute post-treatment sputum weight was higher (p=0.012). In pre-specified subgroups (rhDNase use, age, and disease severity), the treatment differences consistently favoured mannitol. The most common AEs were cough and pulmonary exacerbations. Pulmonary exacerbation AEs were approximately 30% lower in the mannitol group.

Authors' conclusions

In children with CF, inhaled mannitol was associated with significant improvements in lung function and sputum weight, irrespective of rhDNase use, age or disease severity. Inhaled mannitol was well tolerated and was associated with a reduced incidence of pulmonary exacerbation AEs.

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See also

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Keywords

bronchitol; Inhalation OR nebulised; Mannitol; pharmacological_intervention; Powders; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents;