primary studies - published RCT

Long-term inhaled dry powder mannitol in cystic fibrosis: an international randomized study.

Code: PM22198974 **Year:** 2011 **Date:** 2011 **Author:** Aitken ML

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

Double-blind, randomized, controlled trial

Participants

CF patients

Interventions

inhaled mannitol, 400 mg twice a day (n = 192, "treated" group) or 50 mg twice a day (n = 126, "control" group) for 26 weeks, followed by 26 weeks of open-label treatment

Outcome measures

The primary endpoint was absolute change in FEV(1) from baseline in treated versus control groups, averaged over the study period. Secondary endpoints included other spirometric measurements, pulmonary exacerbations, and hospitalization. Clinical, microbiologic, and laboratory safety were assessed

Main results

The treated group had a relative improvement in FEV(1) of 3.75% (P = 0.029) versus the control group. Adverse events and sputum microbiology were similar in both treatment groups. Exacerbation rates were low, but there were fewer in the treated group (hazard ratio, 0.74; 95% confidence interval, 0.42-1.32; P = 0.31), although this was not statistically significant. In the 26-week open-label extension study, FEV(1) was maintained in the original treated group, and improved in the original control group to the same degree

Authors' conclusions

Inhaled mannitol, 400 mg twice a day, resulted in improved lung function over 26 weeks, which was sustained after an additional 26 weeks of treatment. The safety profile was also acceptable, demonstrating the potential role for this chronic therapy for CF.

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See also

Am J Respir Crit Care Med. 2012 Mar 15;185(6):645-52. Epub 2011 Dec 28.

Keywords

Adult; Aged; Child; Inhalation OR nebulised; Mannitol; pharmacological_intervention; placebo; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents;