primary studies - published RCT

Efficacy and safety of inhaled dry-powder mannitol in adults with cystic fibrosis: An international, randomized controlled study.

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

Multicenter, double-blind, randomized, parallel-group, controlled clinical trial

Participants

423 adults (aged â‰¥18 years) with CF, and forced expiratory volume in 1Â second (FEV(1)) 40-90% predicted.

Interventions

Subjects received either mannitol 400 mg or mannitol 50 mg (control), BID via dry-powder inhaler for 26 weeks.

Outcome measures

Primary endpoint: FEV(1) averaged over the 26-week treatment period.

Main results

Of 423 subjects randomized (209 or 214 receiving mannitol 400 mg BID or control, respectively), 373 (88.2%) completed the study, with a similar proportion completing in the two groups. For FEV(1) averaged over 26 weeks, mannitol 400 mg BID was statistically superior to control (adjusted mean difference 54 mL [95% CI 8, 100 mL]; p = 0.020). This was supported by sensitivity analyses of the primary endpoint, and by observed improvements in secondary pulmonary function endpoints (eg, absolute adjusted mean difference in percent predicted FEV(1) averaged over 26 weeks 1.21% [0.07%, 2.36%]; p = 0.037). Adverse events were mainly mild or moderate in severity, with treatment-related adverse events in 15.5 and 12.2% of subjects receiving mannitol 400 mg BID and control, respectively.

Authors' conclusions

In adults with CF, mannitol 400 mg BID inhaled as a dry-powder statistically significantly improved lung function (FEV(1)) compared with control, with this improvement supported by sensitivity analyses and secondary pulmonary function endpoints. Mannitol had a good overall safety and tolerability profile.

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See also

J Cyst Fibros. 2021 Mar 11:S1569-1993(21)00046-1. doi: 10.1016/j.jcf.2021.02.011.

Keywords

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