

*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 ≥18 years) with CF, and forced expiratory volume in 1<sup>st</sup> second (FEV<sub>1</sub>) 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<sub>1</sub> 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<sub>1</sub> 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<sub>1</sub> 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<sub>1</sub>) compared with control, with this improvement supported by sensitivity analyses and secondary pulmonary function endpoints. Mannitol had a good overall safety and tolerability profile.

<http://dx.doi.org/10.1016/j.jcf.2021.02.011>

### **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;