

primary studies - published RCT

# **A Prospective, Randomized, Double-Blind, Parallel-Group, Comparative Effectiveness Clinical Trial Comparing a Powder Vehicle Compound of Vitamin D With an Oil Vehicle Compound in Adults With Cystic Fibrosis.**

**Code:** PM26903303

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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  $\geq 18$  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/10.1177/0148607116629673>

## **See also**

JPEN J Parenter Enteral Nutr. 2016 Feb 22.

## **Keywords**

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