primary studies - published RCT

Inhaled dry powder mannitol in cystic fibrosis: an efficacy and safety study.

Code: PM21478216 **Year:** 2011 **Date:** 2011 **Author:** Bilton D

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

This international phase III study of inhaled dry powder mannitol was a randomised, double-blind, 26-week study, followed by a further 26-week, open-label (OL) extension.

Participants

324 cystic fibrosis (CF) patients

Interventions

patients were randomised, in a 3:2 ratio, to mannitol (400 mg b.i.d.) and control groups.

Outcome measures

The primary efficacy end-point was to determine the change in forced expiratory volume in 1 s (FEV(1)) over the double-blind phase. Secondary end-points included changes in forced vital capacity and pulmonary exacerbations.

Main results

A significant improvement in FEV(1) was seen over 26 weeks (p

Authors' conclusions

Mannitol showed sustained, clinically meaningful benefit in airway function in CF, irrespective of concomitant rhDNase use. Mannitol appears to have an acceptable safety profile for patients with CF.

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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;