primary studies - published RCT

Inhalation of Moli1901 in patients with cystic fibrosis.

Code: PM17494794 **Year:** 2007 **Date:** 2007 **Author:** Grasemann H

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

phase II, placebo-controlled, double-blinded, single-center.

Participants

24 patients with CF and stable lung disease

Interventions

multiple (5 consecutive days), rising-dose (daily dose, 0.5, 1.5, or 2.5 mg of Moli1901) study was conducted to investigate the safety and tolerability of multiple doses of aerosolized inhaled Moli1901

Outcome measures

investigate the safety and tolerability of multiple doses of aerosolized inhaled Moli1901

Main results

Moli1901 was well tolerated in all but one CF patient, in whom a transient significant decrease in FEV(1) developed following inhalation, which resolved spontaneously, and in a second patient in whom transient throat numbness developed during drug inhalation. A significant improvement of FEV(1) was observed in the group receiving treatment with 2.5 mg/d Moli1901 compared to the group receiving placebo (p = 0.01 [Wilcoxon test]). Moli1901 was not detected in the plasma of the highest dose group.

Authors' conclusions

The inhalation of Moli1901 up to a total cumulative dose of 12.5 mg appears to be safe in adult patients with CF. In addition, Moli1901 had a sustained beneficial effect on pulmonary function, which supports further studies of its efficacy in CF patients.

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See also

Chest. 2007 May;131(5):1461-6.

Keywords

Adolescent; Adult; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; Moli1901; pharmacological_intervention; Respiratory System Agents; Lancovutide; Duramycin;