primary studies - published RCT

Levofloxacin inhalation solution (MP-376) in patients with cystic fibrosis with Pseudomonas aeruginosa.

Code: PM21471106 **Year:** 2011 **Date:** 2011 **Author:** Geller DE

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

randomized controlled trial

Participants

151 patients with CF and chronic PA infection

Interventions

MP-376 (120 mg every day, 240 mg every day, 240 mg twice a day) or placebo for 28 days.

Outcome measures

The primary efficacy endpoint was the change in sputum PA density. Secondary endpoints included changes in pulmonary function, the need for other anti-PA antimicrobials, changes in patient-reported symptom scores, and safety monitoring.

Main results

All doses of MP-376 resulted in reduced sputum PA density at Day 28, with MP-376 240 mg twice a day showing a 0.96 log difference compared with placebo (P = 0.001). There was a dose-dependent increase in FEV(1) for MP-376, with a difference of 8.7% in FEV(1) between the 240 mg twice a day group and placebo (P = 0.003). Significant reductions (61-79%) in the need for other anti-PA antimicrobials were observed with all MP-376 treatment groups compared with placebo. MP-376 was generally well tolerated relative to placebo.

Authors' conclusions

Nebulized MP-376was well tolerated and demonstrated significant clinical efficacy in heavily treated patients with CF with PA lung infection.

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See also

Am J Respir Crit Care Med. 2011 Jun 1;183(11):1510-6. Epub 2011 Feb 25.

Keywords

Adult; Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; levofloxacin; Ofloxacin; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Quinolones;