primary studies - published RCT

Randomised placebo controlled trial of non-invasive ventilation for hypercapnia in cystic fibrosis.

Code: PM17675317 **Year:** 2008 **Date:** 2011 **Author:** Young AC

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

RCT

Participants

10 CF subjects

Interventions

single 180-mg doses of two formulations of MP-376, followed by a multiple-dose phase of 240 mg once daily for 7 days.

Outcome measures

Serum and expectorated-sputum samples were assayed for levofloxacin content. Safety was evaluated following the single- and multiple-dose study phases.

Main results

Nebulized MP-376 produced high concentrations of levofloxacin in sputum. The mean maximum plasma concentration (C(max)) ranged between 2,563 and 2,932 mg/liter for 180-mg doses of the 50- and 100-mg/ml formulations, respectively. After 7 days of dosing, the mean C(max) for the 240-mg dose was 4,691 mg/liter. The mean serum levofloxacin C(max) ranged between 0.95 and 1.28 for the 180-mg doses and was 1.71 for the 240-mg dose. MP-376 was well tolerated. Nebulized MP-376 produces high sputum and low serum levofloxacin concentrations. The pharmacokinetics, safety, and tolerability were similar for the two formulations.

Authors' conclusions

MP-376 240 mg (100 mg/ml) is being advanced into late-stage clinical development.

http://dx.doi.org/10.1136/thx.2007.082602

See also

Thorax. 2008 Jan;63(1):72-7. Epub 2007 Aug 3.

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;