primary studies - published RCT

A phase 3, multi-center, multinational, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of levofloxacin inhalation solution (APT-1026) in stable cystic fibrosis patients.

Code: PM26852040 **Year:** 2016 **Date:** 2016 **Author:** Flume PA

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

Randomized, double-blind, placebo controlled trial of 3 dose groups of MP-376 versus placebo for 28 days.

Participants

CF patients > 12 years with chronic P. aeruginosa infection.

Interventions

28-day course of treatment with APT-1026 (levofloxacin inhalation solution, LIS) 240mg or placebo

Outcome measures

Time to exacerbation was the primary endpoint. FEV1 (% predicted) and patient-reported quality of life were among secondary endpoints.

Main results

Baseline demographics for 330 subjects (LIS = 220) were similar although significantly more patients randomized to LIS had experienced multiple exacerbations in the year prior to study entry. There was no statistically significant difference in protocol-defined pulmonary exacerbations between treatment arms. Relative change in FEV1% predicted from baseline was significantly greater for patients randomized to LIS compared to those randomized to placebo (mean difference 1.31%, p = 0.01 [95% CI 0.27, 2.34%]). LIS was well-tolerated, with dysguesia the most frequent adverse event.

Authors' conclusions

LIS did not demonstrate a difference in time to next exacerbation when compared to placebo. Reasons for this result are discussed but may be due to an imbalance in the frequency of prior pulmonary exacerbations between the two groups. An improvement in FEV1 (% predicted) at 28 days was observed and LIS was well tolerated. LIS is safe and has a potential role in the management of CF patients with chronic P. aeruginosa.

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See also

J Cyst Fibros. 2016 Jul;15(4):495-502. doi: 10.1016/j.jcf.2015.12.004. Epub 2016 Feb 4.

Keywords

Adult; aeroquin; Aged; Anti-Bacterial Agents; Child; Inhalation OR nebulised; levofloxacin; pharmacological_intervention; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Quinolones;