primary studies - published RCT

A phase 3, open-label, randomized trial to evaluate the safety and efficacy of levofloxacin inhalation solution (APT-1026) versus tobramycin inhalation solution in stable cystic fibrosis patients

Code: PM25592656 **Year:** 2015 **Date:** 2015 **Author:** Elborn JS

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

multinational, randomized (2:1), non-inferiority study

Participants

CF patients â‰¥12years old with chronic P. aeruginosa infection.

Interventions

APT-1026 (levofloxacin inhalation solution, LIS) vs tobramycin inhalation solution (TIS) over three 28-day on/off cycles.

Outcome measures

Day 28 FEV1 % predicted relative change was the primary endpoint. Time to exacerbation and patient-reported quality of life were among secondary endpoints.

Main results

Baseline demographics for 282 subjects were comparable. Non-inferiority was demonstrated (1.86% predicted mean FEV1 difference [95% CI -0.66 to 4.39%]). LIS was well-tolerated, with dysgeusia (taste distortion) as the most frequent adverse event.

Authors' conclusions

LIS is a safe and effective therapy for the management of CF patients with chronic P. aeruginosa infection.

http://dx.doi.org/10.1016/j.jcf.2014.12.013.

See also

J Cyst Fibros. 2015 Jan 12.

Keywords

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