primary studies - published RCT

Phase II studies of nebulised Arikace in CF patients with Pseudomonas aeruginosa infection.

Code: PM23749840 **Year:** 2013 **Date:** 2013 **Author:** Clancy JP

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

double-blind, randomized, placebo-controlled study

Participants

105 cystic fibrosis patients chronically infected with P aeruginosa.

Interventions

Subjects were randomised to once-daily Arikace (70, 140, 280 and 560 mg; n=7, 5, 21 and 36 subjects) or placebo (n=36) for 28 days.

Outcome measures

Primary outcomes included safety and tolerability. Secondary outcomes included lung function (forced expiratory volume at one second (FEV1)), P aeruginosa density in sputum, and the Cystic Fibrosis Quality of Life Questionnaire-Revised (CFQ-R).

Main results

The adverse event profile was similar among Arikace and placebo subjects. The relative change in FEV1 was higher in the 560 mg dose group at day 28 (p=0.033) and at day 56 (28 days post-treatment, 0.093L+/-0.203 vs -0.032L+/-0.119; p=0.003) versus placebo. Sputum P aeruginosa density decreased >1 log in the 560 mg group versus placebo (days 14, 28 and 35; p=0.021). The Respiratory Domain of the CFQ-R increased by the Minimal Clinically Important Difference (MCID) in 67% of Arikace subjects (560 mg) versus 36% of placebo (p=0.006), and correlated with FEV1 improvements at days 14, 28 and 42 (p

Authors' conclusions

CONCLUSIONS: Once-daily Arikace demonstrated acute tolerability, safety, biologic activity and efficacy in patients with CF with P aeruginosa infection.

http://dx.doi.org/10.1136/thoraxjnl-2012-202230

See also

Thorax. 2013 Sep;68(9):818-25. doi: 10.1136/thoraxjnl-2012-202230. Epub 2013 Jun 8.

Keywords

Amikacin; Anti-Bacterial Agents; arikace; Liposomal amikacin; Bacterial Infections; Infection; Inhalation OR nebulised; pharmacological_intervention; placebo; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Aminoglycosides; Liposomal Amikacin;