

primary studies - published RCT

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

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### 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,  $0.093L\pm0.203$  vs  $-0.032L\pm0.119$ ;  $p=0.003$ ) 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;