

primary studies - published RCT

## Pharmacokinetics of famotidine in patients with cystic fibrosis.

Code: PM9824781

Year: 1998 Date: 2002

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

RCT

### Participants

520 patients with CF and chronic *Pseudomonas aeruginosa* infection

### Interventions

Patients were randomly assigned to receive 24 weeks of placebo or treatment with TSI 300 mg b.i.d., both administered in cycles of 28 days on drug (or placebo) followed by 28 days off, for a total of three cycles.

### Outcome measures

After each on-drug cycle, patients or parents, and physicians, were asked to rate whether the patient's condition was better, unchanged, or worse.

### Main results

There was strong agreement between the paired patient/parent and physician global HRQOL ratings across the three cycles. Regression analyses demonstrated that patients in the TSI group were significantly more likely to report improvements in HRQOL than were patients in the placebo group. This effect was found to be both immediate (end of on-drug cycle 1) and delayed (end of subsequent on-drug cycles 2 and 3) (P

### Authors' conclusions

Results of this study provided consistent evidence that TSI was associated with improved global ratings of HRQOL completed by both patients or parents, and physicians. Although these results are promising, they are limited by the use of a single-item rating of health. Future studies of the effects of TSI should utilize a well-validated, disease-specific measure of HRQOL.

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### See also

J Clin Pharmacol. 1998 Nov;38(11):1010-6.

### Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological\_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;