*primary studies - published RCT*

# Long term effects of denufosol tetrasodium in patients with cystic fibrosis.

**Code:** PM22682898 **Year:** 2012 **Date:** 2015 **Author:** Ratjen F

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

Phase IIb, randomised, double-blind, placebo-controlled study

### Participants

Patients with CF, >/=12 years of age (N=286)

### Interventions

Patients were randomised to ciprofloxacin DPI (32.5 mg (n=93) or 48.75 mg (n=93)), or corresponding placebo (32.5 mg, n=65; 48.75 mg, n=35) twice daily for 28 days.

### Outcome measures

The primary objective was the change in forced expiratory volume in 1 s (FEV1) from baseline (day 0) to end of treatment (day 29) in the intent-to-treat population for ciprofloxacin DPI compared with the corresponding placebo group.

### Main results

The primary effectiveness objective was not met; there were no significant differences in change in FEV1 between ciprofloxacin DPI and the corresponding placebo group for either dose (p=0.154). However, in pooled analyses, FEV1 decline from baseline to treatment end was significantly lower with ciprofloxacin DPI than with placebo (pooled data; p=0.02). Ciprofloxacin DPI showed positive effects on sputum bacterial load and quality of life, but these effects were not maintained at the 4-week follow-up. Ciprofloxacin DPI was well tolerated and there were no significant differences in type/incidence of treatment-emergent adverse events by treatment group (p=0.115).

### Authors' conclusions

Further investigations are needed to determine the full scope of the beneficial effects of ciprofloxacin DPI for patients with CF.

http://dx.doi.org/10.1016/j.jcf.2012.05.003

### See also

J Cyst Fibros. 2012 Dec;11(6):539-49. doi: 10.1016/j.jcf.2012.05.003. Epub 2012 Jun 8.

### Keywords

Anti-Bacterial Agents; Ciprofloxacin; Inhalation OR nebulised; pharmacological_intervention; Powders; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Quinolones;