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primary studies - published RCT

## Denufosal tetrasodium in patients with cystic fibrosis and normal to mildly impaired lung function.

**Code:** PM21169471

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**Author:** Accurso FJ

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

Phase 3, randomized, double-blind, placebo-controlled, 24-week trial

### Participants

A total of 352 patients greater than or equal to 5 years old with cystic fibrosis who had FEV(1) greater than or equal to 75% of predicted normal

### Interventions

patients were randomized to receive inhaled denufosal, 60 mg, or placebo three times daily

### Outcome measures

Mean change from baseline to Week 24 endpoint in FEV(1) (primary efficacy endpoint); secondary endpoints included exacerbation rate and other measures of lung function.

### Main results

Mean change from baseline to Week 24 endpoint in FEV(1) (primary efficacy endpoint) was 0.048 L for denufosal (n = 178) and 0.003 L for placebo (n = 174; P = 0.047). No significant differences between groups were observed for secondary endpoints including exacerbation rate and other measures of lung function. Denufosal was well tolerated with adverse event and growth profiles similar to placebo.

### Authors' conclusions

Denufosal improved lung function relative to placebo in cystic fibrosis patients with normal to mildly impaired lung function.

<http://dx.doi.org/10.1164/rccm.201008-1267OC>

### See also

Am J Respir Crit Care Med. 2011 Mar 1;183(5):627-34. Epub 2010 Dec 17.

### Keywords

Adolescent; Adult; Child; Other drugs; denufosal; pharmacological\_intervention; Inhalation OR nebulised;