primary studies - published RCT

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

Code: PM21169471 **Year:** 2011 **Date:** 2011 **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 denufosol, 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 denufosol (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. Denufosol was well tolerated with adverse event and growth profiles similar to placebo.

Authors' conclusions

Denufosol 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; denufosol; pharmacological_intervention; Inhalation OR nebulised;