primary studies - published RCT

Phase 2 randomized safety and efficacy trial of nebulized denufosol tetrasodium in cystic fibrosis.

Code: PM17446337 **Year:** 2007 **Date:** 2007 **Author:** Deterding RR

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

randomized, double-blind, multi-center, 28-day, phase 2 clinical trial

Participants

89 patients with screening FEV(1) >or= 75% of predicted normal value and not treated with inhaled antibiotics for the past 30 days

Interventions

Patients were randomized to receive one of three doses of denufosol (20, 40, or 60 mg) or placebo (normal saline) administered three times daily.

Outcome measures

safety and efficacy. FEV1, FVC, FEF25-75, adverse events

Main results

89 patients were randomized and received the study drug, 94% completed the study, and 98% were compliant with dosing. All treatments were generally well tolerated, with no dose-response trends observed with respect to safety parameters. The most common adverse event was cough (52% of placebo patients and 47% of denufosol patients). Five patients discontinued early due to adverse events, two on placebo and three on denufosol. Denufosol patients (pooling active doses) had significantly higher changes from baseline in FEV(1) (P = 0.006), FEF(25%-75%) (P = 0.008), FVC (P = 0.022), and FEV(1)/FVC (P = 0.047) than placebo patients at the end of the study.

Authors' conclusions

Denufosol administered three times daily for 28 days appeared to be safe and well tolerated in this population with mild cystic fibrosis and provided preliminary evidence of potential benefit in lung function.

http://dx.doi.org/10.1164/rccm.200608-1238OC

See also

Am J Respir Crit Care Med. 2007 Aug 15;176(4):362-9. Epub 2007 Apr 19.

Keywords

Adolescent; Adult; Child; Other drugs; denufosol; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention;