primary studies - published RCT

Randomized clinical trial of behavioral intervention and nutrition education to improve caloric intake and weight in children with cystic fibrosis.

Code: PM19805710 **Year:** 2009 **Date:** 2012 **Author:** Stark LJ

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

Multicenter, randomized, parallel group double-blind placebo-controlled trial

Participants

CF patients with mild lung function impairment age 5 years and older. Multicenter, conducted at 102 CF care centers in Australia, Canada and the United States. 685 patients were screened for the study and 466 patients (233 in each group) were randomized to study treatment.

Interventions

The active group (n=233) received 60 mg denufosol via inhalation three times daily

Outcome measures

The primary efficacy endpoint was change in FEV(1) in liters from Day 0 to week 48.

Main results

The adjusted mean change in FEV(1) was 40 mL for denufosol and 32 mL for placebo with a resulting treatment effect of 8 mL (95% CI -0.040, 0.056). The average rate of change in FEV(1) percent of predicted over 0 to 48 weeks was -3.04% for placebo vs. -2.30 for denufosol (a difference of 24% relative to placebo) among all patients. The incidence of pulmonary exacerbation was 26% vs. 21% for the placebo and denufosol groups with no differences in the time to first event. The study treatments were well tolerated and there was no evidence of systemic effects in any safety parameter assessed.

Authors' conclusions

In patients with CF treatment with denufosol for 48 weeks did not improve pulmonary function or reduce the incidence of pulmonary exacerbations.

http://dx.doi.org/10.1001/archpediatrics.2009.165

See also

Arch Pediatr Adolesc Med. 2009 Oct;163(10):915-21.

Keywords

Adolescent; Adult; Child; Other drugs; denufosol; pharmacological_intervention; Inhalation OR nebulised;