primary studies - published RCT

Do infants with cystic fibrosis need a protein hydrolysate formula? A prospective, randomized, comparative study.

Code: PM9506640 **Year:** 1998 **Date:** 2002 **Author:** Ellis L

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

Placebo and dual intervention cross-over trial, short-term arm 4 weeks; long-term arm 26 weeks

Participants

44 CF participants (16 males), age range 13 - 37 years. 36 participants finished short-term arm. Initial FEV1 69%

Interventions

Either nebulised albuterol 2.5 mg bd and placebo discus or salmeterol 100 mcg bd by discus and placebo nebuliser

Outcome measures

Changes in spirometry (FEV1, FVC, FEF25-75)measured at baseline, 4 weeks, 12 weeks and 24 weeks Side effects. Need for antibiotic interventions

Main results

Thirty-six out of 44 patients enrolled finished the short-term treatment period, and 19 out of 23 who continued the study also finished the long-term treatment period. There was no significant difference in the mean % change in FEV(1) from baseline to completion of 4 weeks with each drug in the short-term treatment period (0.1% vs. 0.06%, albuterol vs. salmeterol; respectively). In the long-term treatment period, there was a significant decrease from baseline in FEV(1) with albuterol vs. salmeterol, as measured after both 12 and 24 weeks of each treatment (-6.2% vs. 1.8%, P = 0.013 after 12 weeks, and -6.5% vs. 1.7%, P = 0.002, after 24 weeks, respectively). In both treatment periods, salmeterol was well-tolerated. While there were more rescue treatments per patient per week with albuterol than with salmeterol treatment in both the short- and long-term periods (0.67 vs. 0.40 and 1.76 vs. 0.74, respectively), rescue treatments were needed significantly more often for only the long-term period with albuterol compared to salmeterol (P = 0.022). Also, there were more antibiotic interventions with albuterol than with salmeterol treatment in both the short- and long-term periods (25 vs. 10 and 56 vs. 42, respectively); however, antibiotics were needed significantly more often for only the short-term period (P = 0.011). In addition, there was a significantly higher symptom score with albuterol vs. salmeterol treatment during the second half of the long-term period (1.24 vs. 0.89, P = 0.001).

Authors' conclusions

long-term high-dose salmeterol was equally safe and was associated with better pulmonary function, fewer interventions, and fewer respiratory symptoms compared to standard therapy with albuterol in a population of outpatients with mild to moderate CF.

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See also

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Keywords

Adolescent; Adult; Albuterol; Anti-Bacterial Agents; Bronchodilator Agents; High-Dose; pharmacological_intervention; salmeterol; Adrenergic beta-Agonists; Respiratory System Agents;