primary studies - published RCT

A placebo-controlled, double-blind trial of the long-term effects of albuterol administration in patients with cystic fibrosis.

Code: PM9475328 **Year:** 1998 **Date:** 1998 **Author:** König P

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

placebo-controlled study double-blind, cross-over trial

Participants

Only CF patients with clinically detectable lung disease were enrolled. 21 patients finished the study.

Interventions

albuterol (by metered dose inhaler) 180 microg b.i.d. or placebo were given for 6 months each

Outcome measures

Spirometry was monitored at the start, and 3 and 6 months following initiation of each arm of the study. Peak expiratory flow rate (PEFR) was measured twice daily at home before and after study drug administration.

Main results

All spirometric tests showed a significant improvement from start to end of the 6 month treatment with albuterol; there was no significant change on placebo. Forced vital capacity improved by 8.2% and forced expiratory volume in 1 s by 12.1% on albuterol therapy. Nevertheless, there was no significant difference between change on albuterol and change on placebo. Home measurements of PEFR showed a significant improvement of 4.7% on albuterol and a non-significant change of 2.0% on placebo from the first to the last week of treatment. None of the long-term improvements (spirometry or home PEFR) correlated with mean daily bronchodilation. For albuterol, the number of days of hospitalization was less than half that for patients on placebo (1.0/patient on albuterol versus 2.6 on placebo), but this did not reach statistical significance.

Authors' conclusions

These results suggest a beneficial effect from maintenance therapy with albuterol. Bronchodilation alone probably cannot explain the long-term benefits of albuterol, and other mechanisms may play a role. The lack of significant difference between change on albuterol and change on placebo is probably due to too small a number of patients in this study and lack of statistical power.

3.0.CO;2-Q" target="_blank">http://dx.doi.org/10.1002/(SICI)1099-0496(199801)25:1<32::AID-PPUL3>3.0.CO;2-Q

See also

Pediatr Pulmonol. 1998 Jan;25(1):32-6.

Keywords

Adolescent; Albuterol; Bronchodilator Agents; Child; Drug Administration Schedule; Inhalation OR nebulised; pharmacological_intervention; placebo; Adrenergic beta-Agonists; Respiratory System Agents;