primary studies - published RCT

Effect of high-dose ibuprofen in patients with cystic fibrosis.

Code: PM7503838 **Year:** 1995 **Date:** 1995 **Author:** Konstan MW

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

Randomized double-blinded, placebo-controlled study

Participants

85 people with CF aged 5-39 years. Inclusion criteria - people with CF, diagnosed clinically and by sweat test, not treated with intravenous antibiotics in preceding 2 months and with FEV1 at least 60% predicted. 42 (26 male) were in the treatment group and 43 (15 male) in placebo group; age range 5-39 years. Exclusion criteria: systemic or inhaled corticosteroids used within two years of recruitment or inhaled sodium cromoglycate used within 6 months of recruitment. A total of 28 participants withdrew from study, with similar numbers in both groups (15 in treatment group, 13 in placebo group).

Interventions

Participants randomly assigned to receive high-dose oral ibuprofen twice daily for 4 years or placebo twice daily for 4 years. Dose 20-30 mg per kg of body weight, to a maximum of 1600 mg, determined by pharmacokinetic analyses.

Outcome measures

Compliance (pill counts and blood monitoring) Number to complete Adverse events e.g. abdominal pain, conjunctivitis, epistaxis Concomitant therapy Annual rate of change in FEV1, FVC, FEF25-75% Dropout rates Percentage predicted FEV1, FVC, FEF25-75 Number hospital admissions for exacerbations Number hospital days for exacerbations Annual rate of change in percentage ideal body weight Change in Brasfield chest X-ray score over 4-year period Intravenous antibiotics administered at home

Main results

Patients randomly assigned to ibuprofen had a slower annual rate of change in FEV1 than the patients assigned to placebo (mean [+/- SE] slope, -2.17 +/- 0.57 percent vs. -3.60 +/- 0.55 percent in the placebo group; P = 0.02), and weight (as a percentage of ideal body weight) was better maintained in the former group (P = 0.02). Among the patients who took ibuprofen for four years and had at least a 70 percent rate of compliance, the annual rate of change in FEV1 was even slower (-1.48 +/- 0.69 percent vs. -3.57 +/- 0.65 percent in the placebo group, P = 0.03), and this group of patients also had a significantly slower rate of decline in forced vital capacity, the percentage of ideal body weight, and the chest-radiograph score. There was no significant difference between the ibuprofen and placebo groups in the frequency of hospitalization. One patient was withdrawn from the study because of conjunctivitis, and one because of epistaxis related to ibuprofen.

Authors' conclusions

In patients with cystic fibrosis and mild lung disease, high-dose ibuprofen, taken consistently for four years, significantly slows the progression of the lung disease without serious adverse effects.

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See also

N Engl J Med. 1995 Mar 30;332(13):848-54.

Keywords

Adolescent; Adult; Anti-Inflammatory Agents; Artificial Ventilation; Child; High-Dose; Ibuprofen; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Respiratory Tract Diseases; Ventilators; Oral; Anti-Inflammatory Agents - excl Steroids;