

primary studies - published RCT

## High-dose ibuprofen in cystic fibrosis: Canadian safety and effectiveness trial.

**Code:** PM17719932

**Year:** 2007 **Date:** 2007

**Author:** Lands LC

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

Multicenter double-blind placebo-controlled trial. Allocated treatment by a centralized pharmacy using a pre-defined block randomization schedule.

### Participants

142 children with CF aged 6-18 years. Inclusion criteria: FEV1 >60% predicted at time of entry into the trial, with no hospitalizations in the previous 2 months. Exclusion criteria: people who had taken systemic corticosteroids or non-steroidal anti-inflammatory agents for more than 1 month in the past year, had abnormal hepatic, renal, hematologic disorders or coagulopathy, documented evidence of peptic ulcer di 18 participants (9 in each group) did not complete full 2 years of follow up, 11 due to adverse events (4 in treatment group, 7 in placebo group).

### Interventions

All participants underwent a baseline pharmoacokinetic study (baseline every hour for 3 hours), employing 200 mg tablets (Upjohn-Pharmacia) at a dose of 20 to 30 mg/kg to a maximum of 1600 mg.

### Outcome measures

Annual rate of change in FEV1 % predicted, FVC % predicted, anthropometric data, chest radiograph score, number of hospitalizations (and length of stay), adverse effects, compliance, concomitant therapy (antibiotics, inhaled anti-inflammatory agents).

### Main results

The patients in the high-dose ibuprofen group exhibited a significant reduction in the rate of decline of forced vital capacity percent predicted ( $0.07 \pm 0.51$  vs  $-1.62 \pm 0.52$ ;  $P = .03$ ), but not FEV1%. The ibuprofen group also spent fewer days in hospital after adjusting for age ( $1.8$  vs  $4.1$  days per year;  $P = .07$ ). A total of 11 patients (4 in the ibuprofen group and 7 in the placebo group) withdrew due to adverse events.

### Authors' conclusions

High-dose ibuprofen has a significant effect on slowing the progression of lung disease in CF and generally is well tolerated.

<http://dx.doi.org/10.1016/j.jpeds.2007.04.009>

### See also

J Pediatr. 2007 Sep;151(3):249-54. Epub 2007 Jun 26.

### Keywords

Adolescent; Anti-Inflammatory Agents; Child; High-Dose; Ibuprofen; pharmacological\_intervention; Tablets; Anti-Inflammatory Agents - excl Steroids;