primary studies - published RCT

Multicenter randomized controlled trial of withdrawal of inhaled corticosteroids in cystic fibrosis.

Code: PM16556691 **Year:** 2006 **Date:** 2006 **Author:** Balfour-Lynn IM

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

Multicenter randomized double-blind placebo-controlled trial in 18 pediatric and adult UK centers.

Participants

n=84, median age 14.6 yr, mean (SD) FEV1 76% (18); placebo group: n=87, median age 15.8 yr, mean (SD) FEV1 76% (18). Eligibility criteria included age>6.0 yr, FEV1>or=40% predicted, and corticosteroid use>3 mo.

Interventions

During the 2-mo run-in period, all patients received fluticasone; they then took either fluticasone or placebo for 6 mo.

Outcome measures

Test the safety of withdrawal of inhaled corticosteroids with the hypothesis this would not be associated with an earlier onset of acute chest exacerbations.

Main results

There was no difference in time to first exacerbation (primary outcome) with hazard ratio (95% confidence interval) of 1.07 (0.68 to 1.70) for fluticasone versus placebo. There was no effect of age, atopy, corticosteroid dose, FEV1, or Pseudomonas aeruginosa status. There was no change in lung function or differences in antibiotic or rescue bronchodilator use. Fewer patients in the fluticasone group withdrew from the study due to lung-related adverse events (9 vs. 15%); with a relative risk (95% confidence interval) of 0.59 (0.23-1.48) fluticasone versus placebo.

Authors' conclusions

In this study population (applicable to 40% of patients with cystic fibrosis in the UK), it appears safe to consider stopping inhaled corticosteroids. Potential advantages will be to reduce the drug burden on patients, reduce adverse effects, and make financial savings.

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See also

Am J Respir Crit Care Med. 2006 Jun 15;173(12):1356-62. Epub 2006 Mar 23.

Keywords

Adolescent; Adrenal Cortex Hormones; Adult; Androstadienes; Anti-Inflammatory Agents; Bacterial Infections; Child; Hormones; Infection; Inhalation OR nebulised; pharmacological_intervention; placebo; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Steroids; Exacerbation; fluticasone;