primary studies - published RCT

Randomized, double-blind, placebo-controlled, dose-escalating study of aerosolized interferon gamma-1b in patients with mild to moderate cystic fibrosis lung disease.

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

RCT

Participants

66 patients (mean age, 24 years, with mean baseline FEV1 of 74 +/- 20 (SD) percent predicted)

Interventions

sequential dose cohorts inhaling 500 microg IFN-gamma1b, 1,000 microg IFN-gamma1b, or placebo by Respirgard II nebulizer thrice weekly for 12 weeks.

Outcome measures

Sputum bacterial density and spirometry were measured. Safety, antibiotic use, hospitalization, and sputum neutrophils, elastase, DNA, IL-8, and myeloperoxidase were also evaluated.

Main results

One patient had bronchospasm after the first dose of IFN-gamma1b; the overall withdrawal rate was 15% (5 in the placebo group, 2 in the 500-microg IFN-gamma1b group, and 3 in the 1,000 microg IFN-gamma1b group). The 500-microg IFN-gamma1b dose was well-tolerated, but the 1,000-mug dose cohort, who had a higher baseline bacterial density than placebo patients (mean difference, 1.2 log(10) CFU/g sputum, 95% confidence interval (CI), 0.1,2.8, P=0.04), had 24% more hospitalizations for exacerbation than placebo patients (95% CI, 2,45%, P=0.05). There was a 0.12-l difference between the 500-microg IFN-gamma1b and placebo groups with respect to the 12-week change in FEV1 (active group minus placebo group, 95% CI, -0.03,0.26, P=0.11), as compared to a 0.01-l difference between the 1,000-microg IFN-gamma1b and placebo groups (95% CI, -0.16,0.17, P=0.96). No effects of IFN-gamma1b were seen in sputum bacterial density or inflammatory biomarkers at 12 weeks.

Authors' conclusions

Aerosolized IFN-gamma1b did not improve pulmonary function, reduce sputum bacterial density, or affect inflammatory sputum markers in patients with mild-moderate lung disease.

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See also

Pediatr Pulmonol. 2005 Mar;39(3):209-18.

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Dose-Escalating; Drug Administration Schedule; Hospitalization; Hospital care; Immunoregulatory; Infection; Inhalation OR nebulised; Interferon; pharmacological_intervention; placebo; Respiratory Tract Diseases; Respiratory Tract Infections;