primary studies - published RCT

Oral corticosteroid therapy in cystic fibrosis patients hospitalized for pulmonary exacerbation: a pilot study.

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

Randomised 1:1 to receive oral prednisone or oral placebo. Randomisation stratified on study site. Parallel study. 2 centres.

Participants

Treatment group: 24 Individuals with cystic fibrosis aged 10 years or over hospitalised for an acute exacerbation. FEV1 â‰¥ 40%. 12 in treatment group and 12 in placebo. 3 withdrawals from prednisone group (1 prior to starting study drug due to hypertension; 2 for adverse events on day 2 (hyperglycaemia and hypertension)) and 1 withdrawal from placebo group due to sinus surgery on day 8. 7 males, 5 females; mean (SD) 20.3 (10.5) years, median 18.3 years. FEV1 % predicted mean (SD) 69.3 (17.3), median 68.4. P aeruginosa density (log10 cfu/g) mean (SD) 4.3 (3.4), median 4.5. Placebo group: 9 males, 3 females; mean (SD) 21.2 (10.2) years, median 16.5 years. FEV1 % predicted mean (SD) 76.7 (19.0), median 83.5. P aeruginosa density (log10 cfu/g) mean (SD) 6.0 (3.2), median 7.0. Participants in placebo group had higher FEV1 and lower Pseudomonas aeruginosa density at baseline (not statistically significant).

Interventions

Oral prednisone twice daily, total daily dose 2 mg/kg up to a maximum of 60 mg compared to oral placebo (lactose) for 5 days. Tablets of prednisone and placebo were identical on same schedule.

Outcome measures

FEV1, weight, oxygen saturation, symptom scores (modified questionnaire), sputum bacterial density, sputum cell count and differential, sputum interleukin-8, leukotriene B4, adverse events, urine glucose, serum glucose, blood pressure.

Main results

Twelve subjects were randomized to each arm. The slope of FEV(1) between day 1 and day 6 did not differ between evaluable subjects in the prednisone vs placebo groups (52 mL/d vs 51 mL/d, respectively). Mean increase in FEV(1) percentage of predicted did not differ significantly between prednisone vs placebo groups (day 6 [mean +/- SD], 12.2 +/- 5.2% vs 8.1 +/- 10.5%; day 14, 14.7 +/- 8.8% vs 10.2 +/- 11.2%, respectively). Sputum inflammatory markers and symptom scores decreased between day 1 and day 14, but mean values did not differ between groups. Glucosuria occurred in six prednisone subjects, two of whom developed hyperglycemia.

Authors' conclusions

In this pilot study, addition of oral corticosteroids to standard CF pulmonary exacerbation therapy did not result in a statistically significant effect on lung function or sputum markers of inflammation. Based on a trend toward improvement in pulmonary function with prednisone therapy, we obtained information for power calculations for a definitive study: 250 randomized subjects are required to detect a four-percentage-point treatment effect in FEV(1) percentage of predicted at day 14 to discriminate between null and alternative hypotheses.

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See also

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Keywords

Adult; Combined Modality Therapy; Oral; pharmacological_intervention; Prednisolone; Prednisone; Steroids; Exacerbation; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections; Tablets; Anti-Inflammatory Agents;