*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;