primary studies - published RCT

A randomized trial of oral prednisone for cystic fibrosis pulmonary exacerbation treatment.

Code: PM38697648 **Year:** 2024 **Date:** **Author:** Waters V

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

Randomized, double-blind, placebo-controlled trial

Participants

People with cystic fibrosis (pwCF) with PExs not responding to antibiotic therapy.

Interventions

At Day 7, those who had not returned to >90% baseline ppFEV(1) were randomized to adjuvant prednisone 1â€…mgÂ·kg(-1) twice daily (max 60â€…mg/day) or placebo for 7â€…days.

Outcome measures

The primary outcome was the difference in proportion of subjects who recovered >90% baseline ppFEV(1) at Day 14 of IV antibiotic therapy.

Main results

173 subjects were enrolled, with 76 randomized. 50% of subjects in the prednisone group recovered baseline FEV(1) on Day 14 compared to 39% of subjects in the placebo group for a difference of 11% (95% CI -11, 34%, p=0.34). The mean (sd) change in ppFEV(1) from Day 7 to Day 14 was 6.8% predicted (8.8) in the prednisone group and 4.6% (6.9) in the placebo group (mean difference 2.2% predicted 95% CI -1.5, 5.9%, p=0.24). Time to subsequent exacerbation was not prolonged in prednisone treated subjects (HR 0.83, 95% CI 0.45, 1.53; p=0.54).

Authors' conclusions

This study failed to detect a difference in ppFEV(1) recovery between adjuvant oral prednisone and placebo treatment in pwCF not responding at day 7 of IV antibiotic therapy for PExs.

http://dx.doi.org/10.1183/13993003.02278-2023

See also

Eur Respir J. 2024 May 2:2302278. doi: 10.1183/13993003.02278-2023.

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;