primary studies - published RCT

Lumacaftor/Ivacaftor reduces pulmonary exacerbations in patients irrespective of initial changes in FEV1.

Code: PM30146268 **Year:** 2019 **Date:** **Author:** McColley SA

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

Secondary analysis of Standardized Treatment of Pulmonary Exacerbations 2 (STOP2), a large multicenter randomized controlled trial

Participants

Adult PWCF presenting with Pex

Interventions

Corticosteroid treatment e

Outcome measures

The primary outcome measure was the change in percentage predicted FEV(1) (ppFEV(1)). Symptoms, time to next PEx, and the incidence of adverse events (AEs) and serious adverse events (SAEs) were assessed as secondary endpoints. Phenotypic factors associated with the clinical decision to prescribe steroids were also investigated.

Main results

Corticosteroids were prescribed for 168 of 982 PEx events in STOP2 (17%). Steroid prescription was associated with decreased baseline ppFEV(1), increased age, and female sex. Cotreatment with corticosteroids was independent of treatment arm allocation and did not result in greater mean ppFEV(1) response, longer median time to next PEx, or more substantial symptomatic improvement compared with propensity-matched PWCF receiving antibiotics alone. AEs were not increased in corticosteroid-treated PWCF. The total number of SAEs-but not the number of corticosteroid-related or PEx-related SAEs-was higher among patients receiving corticosteroids.

Authors' conclusions

Empiric, physician-directed treatment with systemic corticosteroids, although common, is not associated with improved clinical outcomes in PWCF receiving antibiotics for PEx.

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See also

J Cyst Fibros. 2019 Jan;18(1):94-101. doi: 10.1016/j.jcf.2018.07.011. Epub 2018 Aug 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;