primary studies - published RCT

Ciprofloxacin DPI: a randomised, placebo-controlled, phase IIb efficacy and safety study on cystic fibrosis.

Code: PM26688732 **Year:** 2015 **Date:** 2015 **Author:** Dorkin HL

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

Phase IIb, randomised, double-blind, placebo-controlled study

Participants

Patients with CF, >/=12 years of age (N=286)

Interventions

Patients were randomised to ciprofloxacin DPI (32.5 mg (n=93) or 48.75 mg (n=93)), or corresponding placebo (32.5 mg, n=65; 48.75 mg, n=35) twice daily for 28 days.

Outcome measures

The primary objective was the change in forced expiratory volume in 1 s (FEV1) from baseline (day 0) to end of treatment (day 29) in the intent-to-treat population for ciprofloxacin DPI compared with the corresponding placebo group.

Main results

The primary effectiveness objective was not met; there were no significant differences in change in FEV1 between ciprofloxacin DPI and the corresponding placebo group for either dose (p=0.154). However, in pooled analyses, FEV1 decline from baseline to treatment end was significantly lower with ciprofloxacin DPI than with placebo (pooled data; p=0.02). Ciprofloxacin DPI showed positive effects on sputum bacterial load and quality of life, but these effects were not maintained at the 4-week follow-up. Ciprofloxacin DPI was well tolerated and there were no significant differences in type/incidence of treatment-emergent adverse events by treatment group (p=0.115).

Authors' conclusions

Further investigations are needed to determine the full scope of the beneficial effects of ciprofloxacin DPI for patients with CF.

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See also

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Keywords

Anti-Bacterial Agents; Ciprofloxacin; Inhalation OR nebulised; pharmacological_intervention; Powders; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Quinolones;