primary studies - published RCT

Regular three monthly oral ciprofloxacin in adult cystic fibrosis patients infected with Pseudomonas aeruginosa.

Code: PM8290742 **Year:** 1993 **Date:** 1993 **Author:** Sheldon CD

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

Double-blind RCT. Parallel design.

Participants

40 randomised. 31 completed the trial. Mean age (sd) of 15 participants in the active treatment group: 28.3 years (6.06 years) Mean age (sd) of 16 participants in the placebo group: 24.9 years (5.15 years) Eligible if over 18 years of age and chronically infected with P. aeruginosa. Participants were excluded from the trial if they had P. aeruginosa resistant to CPX in their sputum culture immediately prior to entering the trial, renal insufficiency, an int Sex: active treatment group: 13 males, 2 females; placebo group: 10 males, 6 females. Country: UK

Interventions

CPX (500 mg) tds or an identical placebo for 10 days every 3 months for 4 courses. Time-points reported in the trial: baseline; day 10 (every 3 months) for MIC only; final assessment. Time-points when measurements were taken during the trial: baseline; every 3 months up to 12 months.

Outcome measures

At each visit the participants' clinical symptoms, signs, weight and drug history were recorded*. FEV1* Mortality Adverse effects* FVC* PEF Oxygen saturation Diary card completed listing details of symptoms, sputum volume and PEF. Sputum volume was recorded using a 5-point scale. Sputum samples were cultured at the start and finish (day 10) of each course of tablets. Sputum specimens were collected at each outpatient visit and at the end of each treatment period. Susceptibility of isolates of P. aeruginosa were stored for analysis of MIC at the end of the trial period. Breathlessness was graded by the participants using a 3-point scale*.

Main results

During each course of treatment patients receiving ciprofloxacin reported an improvement in cough, sputum production and peak expiratory flow (PEF) P =

Authors' conclusions

CF patients are likely to benefit from oral ciprofloxacin for exacerbations of respiratory symptoms. However, regular treatment with ciprofloxacin over 1 yr improves PEF but does not reduce the rate of hospital admissions with acute exacerbations of respiratory symptoms.

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See also

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Keywords

Adult; Anti-Bacterial Agents; Bacterial Infections; Ciprofloxacin; Drug Administration Schedule; Infection; Oral; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Quinolones;