

primary studies - published RCT

Sequential ciprofloxacin therapy in pediatric cystic fibrosis: comparative study vs. ceftazidime/tobramycin in the treatment of acute pulmonary exacerbations. The Cystic Fibrosis Study Group.

Code: PM9002118

Year: 1997 **Date:** 1997

Author: Church DA

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

prospective, randomized, double blind study

Participants

130 patients (ages 5 to 17 years)

Interventions

i.v. ciprofloxacin 10 mg/kg every 8 h for 7 days followed by oral ciprofloxacin 20 mg/kg every 12 h for a minimum of 3 days or i.v. ceftazidime 50 mg/kg every 8 h plus i.v. tobramycin 3 mg/kg every 8 h for a minimum of 10 days.

Outcome measures

Clinical, bacteriologic and safety responses were assessed throughout the study.

Main results

All 84 patients (median age, 11 years; range, 5 to 17 years) valid for efficacy in both treatment groups demonstrated clinical improvement. Five patients experienced clinical relapses (3 ciprofloxacin, 2 ceftazidime/tobramycin) by the 2- to 4-week follow-up. Intent-to-treat analysis demonstrated similar clinical findings between the two treatment groups at both the end of therapy and follow-up. Clinical improvement correlated with improvement in pulmonary function studies and the acute clinical scoring system but not with bacteriologic eradication of *Pseudomonas*. DNA profiles demonstrated that irrespective of colony morphology, usually one clonal strain was associated with each patient's pulmonary exacerbation. Treatment-associated musculoskeletal events occurred with equal frequency (22% vs. 21%) in both study drug groups (n = 129), and arthralgias were within the range of rates for cystic fibrosis arthropathy. None of these events required study drug discontinuation.

Authors' conclusions

Sequential i.v./oral ciprofloxacin monotherapy offers a safe and efficacious alternative to standard parenteral therapy for acute pulmonary exacerbations in pediatric cystic fibrosis patients.

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See also

Pediatr Infect Dis J. 1997 Jan;16(1):97-105; discussion 123-6.

Keywords

Adolescent; Anti-Bacterial Agents; Bacterial Infections; Ceftazidime; Child; Ciprofloxacin; Combined Modality Therapy; Infection; pharmacological_intervention; Pneumonia; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Exacerbation; Oral; Cephalosporins; Quinolones; Aminoglycosides;