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.

http://dx.doi.org/10.1097/00006454-199701000-00031

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;