primary studies - published RCT

Efficacy, tolerance, and pharmacokinetics of once daily tobramycin for pseudomonas exacerbations in cystic fibrosis.

Code: PM9713009 **Year:** 1998 **Date:** 2002 **Author:** Vic P

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

Randomised controlled trial.

Participants

Children under 2 years. 209 enrolled, 90 withdrew and 119 completed the study (68 prophylaxis, 51 'as required'). Mean age at enrolment (prophylaxis = 14.1 months, 'as required' = 12.7 months). Followed up for between 5 and 7 years. Data collected at yearly intervals from year 1.

Interventions

Continuous cephalexin versus placebo.

Outcome measures

Primary outcome: Lung function. Secondary outcomes: 1. Growth 2. Inpatient days 3. Courses of 'as required' oral antibiotics 4. Participants with isolates of common pathogens 5. P. aeruginosa

Main results

Of 209 children enrolled, 119 completed a 5- to 7-year course of therapy. Mean age at enrollment was 15.6 and 14.1 months in the cephalexin and placebo groups, respectively. Respiratory cultures from children treated with cephalexin were significantly less likely to be positive for S aureus (6.0% vs 30.4%; P

Authors' conclusions

Although long-term prophylaxis with cephalexin successfully delayed the acquisition of S aureus, it enhanced colonization with P aeruginosa and did not lead to clinically significant improvement in major health outcomes. These data do not support routine antistaphylococcal prophylaxisin otherwise healthy infants and young children with CF.

http://dx.doi.org/10.1136/adc.78.6.536

See also

Arch Dis Child. 1998 Jun;78(6):536-9.

Keywords

Anti-Bacterial Agents; Bacterial Infections; Cephalexin; Child; Cyclosporin; Immunosuppressive Agents; Infant; Infection; pharmacological_intervention; Pneumonia; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Staphylococcus aureus; Continuous; Cephalosporins;