primary studies - published RCT

Comparative efficacy and safety of 4 randomized regimens to treat early Pseudomonas aeruginosa infection in children with cystic fibrosis.

Code: PM21893650 **Year:** 2011 **Date:** 2011 **Author:** Treggiari MM

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

Randomized controlled trial. Multicenter trial in the United States. Intention-to-treat analysis

Participants

304 children with cystic fibrosis aged 1 to 12 years within 6 months of P aeruginosa detection.

Interventions

Participants were randomized to 1 of 4 antibiotic regimens for 18 months (six 12-week quarters) between December 2004 and June 2009. Participants randomized to cycled therapy received tobramycin inhalation solution (300 mg twice a day) for 28 days, with oral ciprofloxacin (15-20 mg/kg twice a day) or oral placebo for 14 days every quarter, while participants randomized to culture-based therapy received the same treatments only during quarters with positive P aeruginosa cultures.

Outcome measures

exacerbation rates, P aeruginosa- positive culture. Adverse events

Main results

There was no interaction between treatments. There were no statistically significant differences in exacerbation rates between cycled and culture-based groups (hazard ratio, 0.95; 95% confidence interval [CI], 0.54-1.66) or ciprofloxacin and placebo (hazard ratio, 1.45; 95% CI, 0.82-2.54). The odds ratios of P aeruginosa- positive culture comparing the cycled vs culture-based group were 0.78 (95% CI, 0.49-1.23) and 1.10 (95% CI, 0.71-1.71) comparing ciprofloxacin vs placebo. Adverse events were similar across groups.

Authors' conclusions

No difference in the rate of exacerbation or prevalence of P aeruginosa positivity was detected between cycled and culture-based therapies. Adding ciprofloxacin produced no benefits.

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See also

Archives of pediatrics & adolescent medicine

Keywords

child; Anti-Bacterial Agents; Bacterial Infections; Infection; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; tobramycin; ciprofloxacin; pharmacological_intervention; Oral; Inhalation OR nebulised; Quinolones; Aminoglycosides;