

primary studies - published RCT

## Comparison of a beta-lactam alone versus beta-lactam and an aminoglycoside for pulmonary exacerbation in cystic fibrosis.

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**Author:** Smith AL

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

Double-blind, Parallel trial.

### Participants

37 males, 39 females, mean age 16.3 years. 111 participants enrolled, 35 withdrawn. 76 participants in total aged 6 - 18 years. PsA colonised. Group 1 (azlocillin): 33 participants (19 male) mean (SD) age 16.07 (7.4) years Group 2 (azlocillin & tobramycin): 43 participants (18 male) mean (SD) age 16.53 (6.9) years

### Interventions

Azlocillin 450 mg/kg/day, 4-hourly plus placebo vs azlocillin plus tobramycin 240 mg/m2/day, 6-hourly, 14 days course.

### Outcome measures

Lung function, time to next admission, symptom scores, adverse events, bacteriology, inflammatory markers, resistant strains.

### Main results

No significant difference was seen between the 2 treatment groups in clinical evaluation, sputum DNA concentration, forced vital capacity, forced expiratory volume in second 1, or peak expiratory flow rate at the end of treatment (33 receiving azlocillin alone and 43 both antibiotics); adverse reactions were equivalent in each group. Sputum *P. aeruginosa* density decreased more with combination therapy ( $P = .034$ ). On follow-up evaluation, an average of 26 days after the end of treatment, all outcome indicators had worsened in both groups. Time to readmission for a new pulmonary exacerbation was significantly longer in the group receiving azlocillin plus tobramycin ( $P$

### Authors' conclusions

the combination of a beta-lactam and an aminoglycoside produces a longer clinical remission than a beta-lactam alone and slightly better initial improvement.

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### See also

J Pediatr. 1999 Apr;134(4):413-21.

### Keywords

Adolescent; Aminoglycosides; Anti-Bacterial Agents; Azlocillin; Bacterial Infections; Child; Combined Modality Therapy; Infection; Intravenous; Penicillins; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Exacerbation;