

primary studies - published RCT

## Early anti-pseudomonal acquisition in young patients with cystic fibrosis: rationale and design of the EPIC clinical trial and observational study'.

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

The Early Pseudomonas Infection Control (EPIC) program consists of two studies, a randomized multicenter trial in CF patients ages 1-12 years at first isolation of Pa from a respiratory culture, and a longitudinal cohort study enrolling Pa-negative patients.

### Participants

patients ages 1-12 years at first isolation of Pa from a respiratory culture (RCT, 306 patients), Pa-negative patients (longitudinal cohort study, 1787 patients)

### Interventions

Using a factorial design, trial participants are assigned for 18 months to either anti-pseudomonal treatment on a scheduled quarterly basis (cycled therapy) or based on recovery of Pa from quarterly respiratory cultures (culture-based therapy). The study drugs include inhaled tobramycin (300 mg BID) for 28 days, combined with either oral ciprofloxacin (15-20 mg/kg BID) or oral placebo for 14 days.

### Outcome measures

The primary endpoints of the trial are the time to pulmonary exacerbation requiring IV antibiotics or hospitalization for respiratory symptoms, and the proportion of patients with new Pa-positive respiratory cultures during the study. The broad goals of the observational study are to describe the risk factors and outcomes associated with early acquisition of Pa.

### Authors' conclusions

These companion studies will provide valuable epidemiological and microbiological information on early CF lung disease and Pa acquisition, and safety and clinical efficacy data on anti-pseudomonal treatment strategies for early Pa infections in the airways of young children with CF.

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### See also

Contemp Clin Trials. 2009 May;30(3):256-68. Epub 2009 Jan 15.

### Keywords

Anti-Bacterial Agents; Bacterial Infections; Child; Ciprofloxacin; Combined Modality Therapy; Drug Administration Schedule; Infant; Infection; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Inhalation OR nebulised; Oral; Quinolones; Aminoglycosides;