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'.

Code: PM19470318 **Year:** 2009 **Date:** 2009 **Author:** Treggiari MM

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.

http://dx.doi.org/10.1016/j.cct.2009.01.003

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;