primary studies - published RCT

Defining a pulmonary exacerbation in cystic fibrosis.

Code: PM11562614 **Year:** 2001 **Date:** 2001 **Author:** Rosenfeld M

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

randomized, controlled trial

Participants

246 patients enrolled in the placebo arm of a randomized, controlled trial of tobramycin for inhalation

Interventions

tobramycin for inhalation

Outcome measures

Physician-investigators completed pulmonary exacerbations (PEx) questionnaires on all subjects at scheduled intervals during the 6-month study, indicating new or worsening symptoms, physical examination findings, and impression of PEx status (presence or absence and severity). Logistic regression was used to assess the relative importance of each of the characteristics in predicting a PEx

Main results

2 PEx scores that use easily ascertained symptoms and chest examination findings were developed; one also includes change in forced expiratory volume in 1 second over the preceding month. Both scores were sensitive and specific for predicting the presence of a PEx (sensitivity, 86%; specificity, 86%). The scores were validated in subjects in the intervention arm of the trial.

Authors' conclusions

the proposed PEx score might serve as a standardized outcome measure for future clinical trials in cystic fibrosis, allowing meaningful comparisons of study results.

http://dx.doi.org/10.1067/mpd.2001.117288

See also

J Pediatr. 2001 Sep;139(3):359-65.

Keywords

Adult; Anti-Bacterial Agents; Inhalation OR nebulised; pharmacological_intervention; Respiratory Tract Diseases; Tobramycin; Bacterial Infections; Respiratory Tract Infections; Infection; Exacerbation; Aminoglycosides;