primary studies - published RCT

Phase 2 randomized safety and efficacy trial of nebulized denufosol tetrasodium in cystic fibrosis.

Code: PM17446337 **Year:** 2007 **Date:** 2011 **Author:** Deterding RR

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

open-label study, randomized

Participants

553 patients aged >/=6 years

Interventions

patients were randomized 3:2 to TIP (total 112mg tobramycin) via the Novartis T-326 Inhaler or TIS 300mg/5mL via PARI LC® PLUS nebulizer twice daily for three treatment cycles (28 days on-drug, 28 days off-drug).

Outcome measures

Safety, efficacy, and treatment satisfaction outcomes were evaluated.

Main results

TIP was generally well-tolerated; adverse events were similar in both groups. The rate of cough suspected to be study drug related was higher in TIP-treated patients (TIP: 25.3%; TIS: 4.3%), as was the overall discontinuation rate (TIP: 26.9%; TIS: 18.2%). Increases in FEV(1)% predicted from baseline to Day 28 of Cycle 3 were similar between groups; the mean reduction in sputum P. aeruginosa density (log(10) CFU/g) on Day 28 of Cycle 3 was also comparable between groups. Administration time was significantly less for TIP (mean: 5.6 versus 19.7min, p

Authors' conclusions

TIP has a safety and efficacy profile comparable with TIS, and offers a far more convenient treatment option for pseudomonas lung infection in CF.

http://dx.doi.org/10.1164/rccm.200608-1238OC

See also

Am J Respir Crit Care Med. 2007 Aug 15;176(4):362-9. Epub 2007 Apr 19.

Keywords

Adolescent; Adult; Aged; Anti-Bacterial Agents; Bacterial Infections; Child; Drug Administration Schedule; Infection; Inhalation OR nebulised; pharmacological_intervention; Powders; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;