primary studies - published RCT

Ease of use of tobramycin inhalation powder compared with nebulized tobramycin and colistimethate sodium: a crossover study in cystic fibrosis patients with pulmonary Pseudomonas aeruginosa infection

Code: PMC5933634 **Year:** 2017 **Date:** 2017 **Author:** Greenwood J

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

Real-world, open-label, crossover, interventional phase IV study

Participants

CF patients aged >=6 years with forced expiratory volume in 1 second (FEV1) >=25% to

Interventions

Patients were assigned to one of the three treatment arms in Cycle 1; all patients received TIP in Cycle 2. Each cycle consisted of 28 days on and 28 days off the treatment.

Outcome measures

Total administration time, which included device setup and cleaning, patients with contaminated devices, treatment satisfaction, assessed by the Treatment Satisfaction Questionnaire for Medication and ACCEPT questionnaire, adverse events.

Main results

A total of 60 patients [mean (standard deviation) age, 27.6 (8.4) years] were allocated to three treatment arms [TIS/TIP (n = 14); COLI/TIP (n = 28); TIP/TIP (n = 18)] in Cycle 1. The mean total administration time, which included device setup and cleaning, in Cycle 1 versus Cycle 2 for TIS/TIP, COLI/TIP, and TIP/TIP arms were 37.0 versus 5.0 min, 16.4 versus 3.8 min, and 4.2 versus 3.4 min, respectively. The difference in mean total administration time was significantly shorter in Cycle 2 than in Cycle 1 for TIS/TIP ($p = 0.0112$) and COLI/TIP ($p = 0.0016$) arms. Overall, 12 patients were found to have contaminated devices across the two treatment cycles. In the TIP/TIP arm, no contamination of the T-326 inhaler was observed in either cycle. Treatment satisfaction, assessed by the Treatment Satisfaction Questionnaire for Medication and ACCEPT questionnaire, was better overall for TIP compared with TIS and COLI. There were no unexpected adverse events and most were mild or moderate in intensity.

Authors' conclusions

The T-326 inhaler used to deliver TIP was easy to use, required shorter total administration time, and was much less frequently contaminated than the nebulizers. The safety findings observed for TIP were generally consistent with its established safety profile.

http://dx.doi.org/10.1164/10.1177/1753465817710596

See also

Therapeutic advances in respiratory disease

Keywords

Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Colistin; Tobramycin; Exacerbation; Aminoglycosides; other anti-bacterial agents; colistimethate; Powders; Child; Adolescent; Adult;