primary studies - published RCT

Efficiency of pulmonary administration of tobramycin solution for inhalation in cystic fibrosis using an improved drug delivery system.

Code: PM12527599 **Year:** 2003 **Date:** 2003 **Author:** Geller DE

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

Open-label, randomized, multicenter, single-dose, three-period, four-treatment, active- control, crossover trial

Participants

Fifty-three patients >or= 12 years of age with a confirmed diagnosis of CF, the ability to expectorate sputum, and FEV(1) of >or= 40% of predicted.

Interventions

tobramycin solution for inhalation (TSI) administered with a new-generation aerosol device, the AeroDose 5.5 RP inhaler (Aerogen; Mountain View, CA) vs with the approved PARI LC PLUS nebulizer (PARI Respiratory Equipment; Monterey, CA) with Pulmo-Aide compressor (DeVilbiss Corp; Somerset, PA). Subjects inhaled three single doses of TSI at 1-week intervals, as follows: conventional control treatment, 300 mg via the PARI LC PLUS; and two of three experimental treatments, 30, 60, or 90 mg via the AeroDose.

Outcome measures

FEV1 (pre and 30 minutes following dose). Sputum concentration of tobramycin (pre, 10 min, 1, 2, 4 & 8 hours). Serum levels of tobramycin (pre, 10 min, 1, 2, 4 & 8 hours). Nebulisation time. Urinary tobramycin concentration (pre, 0 to 8hours, 8 to 24 hours) Adverse events

Main results

There were no significant differences between treatments in the change in FEV(1) 30 min after dosing or in the frequency of adverse events. Sputum and serum levels of tobramycin produced by the AeroDose 90-mg dose treatment approximated those achieved with the PARI LC PLUS 300-mg dose treatment. Nebulization times using the AeroDose inhaler were

Authors' conclusions

Compared with the standard nebulizer, the AeroDose safely achieved an approximately threefold greater efficiency in the delivery of TSI to the lungs in less than half the time.

http://publications.chestnet.org/data/Journals/CHEST/21987/28.pdf

See also

Chest. 2003 Jan;123(1):28-36.

Keywords

Anti-Bacterial Agents; Bacterial Infections; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; non pharmacological intervention - devices OR physiotherapy; Aminoglycosides;