primary studies - published RCT

Copper enzyme activities in cystic fibrosis before and after copper supplementation plus or minus zinc.

Code: PM14681839 **Year:** 2004 **Date:** 2008 **Author:** Best K

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

open, randomized, crossover single dose pilot study

Participants

10 CF patients (>18 years)

Interventions

Tobramycin solution for inhalation (TSI): Tobramycin 300 mg via Pari LC plus with 1. CR60 compressor vs 2. Portaneb® compressor.

Outcome measures

Participant experience (questionnaire) Nebulisation time Tobramycin serum concentration Pharmacokinetics (Cmax) Pulmonary deposition (AUC0-6) Respiratory function Medication osmolality (ampoule and residual in nebuliser)

Main results

It was found that values of Cmax and AUC0-6 were higher with the CR60 than with the PortaNeb: 0.70 versus 0.54 mg/L, p = 0.005, and 2.54 versus 2.01 h.mg/L, p = 0.017, respectively. Tmax after use of the CR60 appeared earlier (0.64 vs. 0.85 h, p = 0.005). Transient airway narrowing was measured in three patients (2 x PN;1 x CR60) versus subjective chest tightness in seven patients (CR60 > PN). A shorter nebulization time for CR60 of 13.2 min compared to PN 16.1 min (p = 0.022) was observed, which was the main reason why patients preferred the CR60 (n = 7). No toxic serum levels were reached after inhalation of TSI.

Authors' conclusions

The CR60 compressor may seem advantageous based on a higher lung deposition and a shorter nebulization time, but a study in a large CF population to provide information on a possible higher risk of toxicity of TSI is called for.

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See also

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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;