primary studies - published RCT

Role of Tris-CaEDTA as an adjuvant with nebulised tobramycin in cystic fibrosis patients with Pseudomonas aeruginosa lung infections: A randomised controlled trial.

Code: PM33341406 **Year:** 2020 **Date:** 2020 **Author:** Puvvadi R

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

Double-blind, randomised controlled trial

Participants

25 patients with P. aeruginosa infection admitted to two CF centres for treatment of an acute pulmonary exacerbation

Interventions

Patients) were randomly assigned to receive either 75 mg CaEDTA in Tris-buffered saline or placebo (Tris-buffered saline) nebulised in combination with 250 mg tobramycin twice daily for six weeks followed with four week safety follow-up.

Outcome measures

Primary endpoints were safety, tolerability, and bacterial density of P. aeruginosa. A secondary endpoint was lung function.

Main results

The study drug was well tolerated with adverse events comparable in both groups. The mean (SD) reduction in sputum P. aeruginosa count (log(10) CFU/g) in the CaEDTA vs placebo group was 2·05 (2·57) vs 0·82 (2·71) at two weeks relative to admission (p = 0·39). The mean improvement in ppFEV(1) was 16 vs 5 (p = 0·16); 11 vs 2 (p = 0·28); and 6 vs 2 percentage points (p = 0·47) at two, six, and ten weeks in CaEDTA and placebo groups, respectively.

Authors' conclusions

In this pilot study in CF patients, an increase in the reduction of sputum density of P. aeruginosa and an increase in ppFEV(1) was observed in the group of patients who received Tris-CaEDTA added to inhaled tobramycin compared to the group who received inhaled tobramycin alone, although these differences were not statistically significant. The treatment was also shown to be safe.

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See also

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Keywords

Anti-Bacterial Agents; Pseudomonas aeruginosa; Pseudomonas; Tobramycin; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Airway clearance technique; Vibration; Aminoglycosides; oscillating devices; Chest physiotherapy;