primary studies - published RCT

Testing the effects of combining azithromycin with inhaled tobramycin for P. aeruginosa in cystic fibrosis: a randomised, controlled clinical trial.

Code: PM34706982 **Year:** 2021 **Date:** 2021 **Author:** Nichols DP

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

Prospective, randomised, placebo-controlled, double-blind trial

Participants

People with cystic fibrosis and Pseudomonas aeruginosa airway infection.

Interventions

Inhaled tobramycin and oral azithromycin. This trial was done to test the effects of combining azithromycin with inhaled tobramycin in people already using inhaled tobramycin.

Outcome measures

Clinical and microbiological outcomes. Forced expiratory volume in one second (FEV(1)) and P. aeruginosa. Secondary clinical outcomes: patient-reported symptom scores, weight and need for additional antibiotics

Main results

Over a 6-week period, including 4â€‰weeks of inhaled tobramycin, the relative change in FEV(1) did not statistically significantly differ between groups (azithromycin (n=56) minus placebo (n=52) difference: 3.44%; 95%â€‰CI: -0.48 to 7.35; p=0.085). Differences in secondary clinical outcomes, including patient-reported symptom scores, weight and need for additional antibiotics, did not significantly differ. Among the 29 azithromycin and 35 placebo participants providing paired sputum samples, the 6-week change in P. aeruginosa density differed in favour of the placebo group (difference: 0.75 log(10) CFU/mL; 95%â€‰CI: 0.03 to 1.47; p=0.043).

Authors' conclusions

Despite having greater reduction in P. aeruginosa density in participants able to provide sputum samples, participants randomised to placebo with inhaled tobramycin did not experience significantly greater improvements in lung function or other clinical outcomes compared with those randomised to azithromycin with tobramycin.

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See also

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Keywords

Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Colonization; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Monobactams; Powders; Tobramycin; Aminoglycosides; Exacerbation; Azithromycin; Macrolides; Anti-Inflammatory Agents; Anti-Inflammatory Agents - excl Steroids;