

Other Reviews - - Other Review

A RCT to explore the effectiveness of supporting adherence to nebuliser medication in adults with cystic fibrosis: fidelity assessment of study interventions.

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

We included randomized placebo controlled trials that assessed the long-term effects of azithromycin treatment on pulmonary function tests, respiratory infections, antibiotic use, and hospitalizations in patients with CF. We included trials that compared different regimens of azithromycin only with placebo.

List of included studies (4)

Equi 2002; Wolter J 2002; Saiman L 2003; Clement A 2006

Participants

4 RCT

Interventions

randomized placebo controlled trials that assessed the long-term effects of azithromycin treatment on pulmonary function tests, respiratory infections, antibiotic use, and hospitalizations in patients with CF. We included trials that compared different regimens of azithromycin only with placebo. Trials that were not randomized, or that compared azithromycin against active control were excluded

Outcome measures

The primary outcome assessed was the impact of azithromycin on lung function deterioration (percentage change in FEV1 and FVC). Secondary outcomes included: number of acute pulmonary exacerbations, number of oral or intravenous additional courses of antibiotics, changes in inflammatory markers, impact on the frequency of the newly positive sputum cultures, requirement for new hospitalizations, adverse effects from azithromycin, and patients' quality of life

Main results

Four RCTs were included in the review (n=368). All of the trials had a Jadad score of 4 (no further details were reported). Azithromycin was associated with a significant increase in FEV1 (MD 3.53%, 95% CI 0.00 to 7.07; four RCTs) and FVC compared with placebo (MD 4.24%, 95% CI 2.02 to 6.45; four RCTs). There was some heterogeneity for FEV1 (I²=38%) and none for FVC. For FVC the difference between groups was not significant in trials with a low proportion of *Pseudomonas*. No significant FEV1 or FVC changes were found at one to three months follow-up. Large amounts of heterogeneity meant studies could not be combined for secondary efficacy outcomes. Three trials reported a significant decrease in the number of antibiotic courses (no further details were reported). The risk of gastrointestinal effects was higher with azithromycin (RR 1.72 95% CI 1.33 to 2.21). The main side effects reported were nausea (RR 2.04, 95% CI 1.19 to 3.45) and diarrhoea (RR 2.12, 95% CI 1.10 to 4.08), which were significantly higher with azithromycin than with placebo. There was no evidence of publication bias (p=0.31).

Authors' conclusions

This review found that azithromycin improved lung function in patients with cystic fibrosis, especially those colonised by *Pseudomonas*. Nausea and diarrhoea were more frequent with azithromycin. The small number of studies, possibility of missed studies and lack of details of the review process made the reliability of the authors' conclusions unclear. Azithromycin improved lung function in patients with cystic fibrosis, especially in those colonised by *Pseudomonas*. Nausea and diarrhoea were more frequent with azithromycin. The authors stated that more studies were needed to investigate the appropriate time to initiate therapy, the best dosing regimen and the subgroup of patients that would benefit most.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Azithromycin; Child; pharmacological_intervention; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Hospitalization; Macrolides; Anti-Inflammatory Agents; Anti-Inflammatory Agents - excl Steroids;