primary studies - published RCT

Effect of azithromycin on pulmonary function in patients with cystic fibrosis uninfected with Pseudomonas aeruginosa: a randomized controlled trial.

Code: PM20442386 **Year:** 2010 **Date:** 2010 **Author:** Saiman L

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

Multi-centre placebo-controlled parallel design.

Participants

Of the 324 participants screened, 260 were randomized and received study drug. The active group (n = 131); the placebo group (n = 129). Eligibility criteria included age of 6 to 18 years, a forced expiratory volume in the first second of expiration (FEV(1)) of at least 50% predicted, and negative respiratory tract cultures for P. aeruginosa for at least 1 year. Randomization was stratified by age of 6 to 12 years vs 13 to 18 years and by CF center.

Interventions

Azithromycin (250 mg 3 times a week, increased to 500, if weight >36 kg) versus placebo; for 168 days.

Outcome measures

Primary: relative change in FEV1 from baseline.

Main results

The mean (SD) age of participants was 10.7 (3.17) years. The mean (SD) FEV(1) at baseline and 168 days were 2.13 (0.85) L and 2.22 (0.86) L for the azithromycin group and 2.12 (0.85) L and 2.20 (0.88) L for the placebo group. The difference in the change in FEV(1) between the azithromycin and placebo groups was 0.02 L (95% confidence interval [CI], -0.05 to 0.08; P = .61). None of the exploratory pulmonary function end points were statistically significant. Pulmonary exacerbations occurred in 21% of the azithromycin group and 39% of the placebo group. Participants in the azithromycin group had a 50% reduction in exacerbations (95% CI, 31%-79%) and an increase in body weight of 0.58 kg (95% CI, 0.14-1.02) compared with placebo participants. There were no significant differences between groups in height, use of intravenous or inhaled antibiotics, or hospitalizations. Participants in the azithromycin group had no increased risk of adverse events, but had less cough (-23% treatment difference; 95% CI, -33% to -11%) and less productive cough (-11% treatment difference; 95% CI, -19% to -3%) compared with placebo participants.

Authors' conclusions

In children and adolescents with CF uninfected with P. aeruginosa, treatment with azithromycin for 24 weeks did not result in improved pulmonary function.

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See also

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Keywords

Adolescent; Anti-Bacterial Agents; Azithromycin; Bacterial Infections; Child; Hospitalization; Hospital care; Infection; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Macrolides; Anti-Inflammatory Agents; Organization; Anti-Inflammatory Agents - excl Steroids;