primary studies - published RCT

Long-term daily high and low doses of azithromycin in children with cystic fibrosis: a randomized controlled trial.

Code: PM19818694 **Year:** 2010 **Date:** 2010 **Author:** Kabra SK

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

Randomised study comparing 2 doses of azithromycin.

Participants

Children with CF (5-18 years). 56/105 children screened were randomised, 47 completed 12 months follow-up.

Interventions

High (15 mg/kg/day) versus low (5 mg/kg/day) dose of azithromycin for 12 months.

Outcome measures

Change in FEV1 (% predicted), pulmonary exacerbation (hospitalisation), microbiology, antibiotic use.

Main results

56 children (28 in high dose group and 28 in low dose group) were enrolled. 47 (24 and 23 children in low and high dose groups) completed 12months of follow up. There was no difference in clinical scores, FEV(1), pulmonary exacerbation rates between the two groups at baseline, at 6 months and at 12 months. Per protocol analysis revealed that pulmonary exacerbation increased after discontinuing AZM and there was significantly more increase after 12 months of enrolment in children getting high dose azithromycin. There was no improvement in FEV(1) in either group at the end of treatment period. Children tolerated well daily low and high AZM dose for 6 months. There was no significant side effect of azithromycin.

Authors' conclusions

In this randomized controlled trial, we did not find differences in the effect of 2 doses (5mg/kg/day or 15mg/kg/day) of AZM on change in percentage predicted FEV(1), clinical scores, Pseudomonas colonization rates, pulmonary exacerbations and need for antibiotics. There was an increase in exacerbations after stopping azithromycin in both groups. Results also suggest that the decrease in the incidence of LRTI persists only till 6 months after discontinuing azithromycin.

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See also

J Cyst Fibros. 2010 Jan;9(1):17-23. Epub 2009 Oct 8.

Keywords

Anti-Bacterial Agents; Azithromycin; Bacterial Infections; Child; Infection; pharmacological_intervention; Pneumonia; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Staphylococcus aureus; Low-Dose; Macrolides; Anti-Inflammatory Agents; Anti-Inflammatory Agents - excl Steroids;