primary studies - published RCT

Open-label, follow-on study of azithromycin in pediatric patients with CF uninfected with Pseudomonas aeruginosa.

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

The authors previously performed a randomized placebo-controlled trial (Saiman 2010 - PM20442386) to examine the effects of azithromycin in children and adolescents 6-18 years of age with cystic fibrosis uninfected with Pseudomononas aeruginosa; they now report the results of the open-label, follow-on study to assess durability of response to azithromycin and continued safety and tolerability.

Participants

Children and adolescents 6-18 years of age with cystic fibrosis uninfected with Pseudomononas aeruginosa. Of 174 eligible participants, 146 (83.9%) enrolled in the open-label study.

Interventions

Eligible participants were enrolled in a 24-week open-label study of azithromycin to compare efficacy and safety endpoints during the placebo-controlled trial versus open-label study in two groups: participants initially on azithromycin continued azithromycin (azithromycin-azithromycin) and participants initially on placebo who then received azithromycin (placebo-azithromycin). As in the placebo-controlled trial, the azithromycin dose in the open-label study was 250 mg Monday-Wednesday-Friday for participants weighing 18-35.9 kg and 500 mg Monday-Wednesday-Friday for participants weighing 36 kg or greater.

Outcome measures

durability of response to azithromycin, safety and tolerability. Lung function, exacerbations, weight gain, adverse events

Main results

No significant improvements in lung function were observed within either group. There were no differences in outcomes in the placebo-azithromycin group during the placebo-controlled versus open-label phase. The azithromycin-azithromycin group had comparable odds of experiencing an exacerbation during the two phases (OR 1.6, CI(95) 0.8, 3.0) and stable weight gain, but new oral antibiotics were initiated more frequently during the open-label study (OR 1.9, CI(95) 1.0, 3.5). In both groups, adverse event rates were comparable during the placebo-controlled and open-label study and treatment-emergent pathogens were rare.

Authors' conclusions

During the open-label study, we observed continued durability of treatment response to azithromycin, as measured by pulmonary exacerbations and continued weight gain, although use of oral antibiotics increased. There were no new safety concerns. Currently available data suggest that azithromycin reduces exacerbations and improves weight gain for 6-12 months among children and adolescents with CF uninfected with P. aeruginosa.

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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;