primary studies - published RCT

Azithromycin for Early Pseudomonas Infection in Cystic Fibrosis: The Optimize Randomized Trial.

Code: PM29890086 **Year:** 2018 **Date:** 2018 **Author:** Mayer-Hamblett N

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

Multicenter, double-blind, randomized, placebo-controlled trial

Participants

Children with CF ages 6 mo -18 years with early Pa, defined as either a first lifetime documented Pa culture or a Pa-positive culture after at least two years of negative cultures.

Interventions

Azithromycin (AZ) or placebo was given three times weekly in combination with standardized tobramycin inhalation solution (TIS) therapy, consisting of 1-2 courses of 28 days TIS and subsequent 28-day treatments only at times a quarterly oropharyngeal culture was positive for Pa.

Outcome measures

The primary endpoint was time to first protocol-defined PE requiring antibiotics. Secondary endpoints included safety, clinical and microbiologic outcomes such as time to Pa recurrence.

Main results

221 participants (111 placebo, 110 azithromycin) out of a planned 274 were enrolled. Enrollment was stopped early by the National Heart, Lung, and Blood Institute (NHLBI) because the trial had reached the pre-specified interim boundary for efficacy. The risk of PEx was reduced by 44% in the azithromycin group as compared to placebo (hazard ratio [HR]: 0.56, 95% CI:0.37,0.83, p=0.004). Weight increased by 1.27 kg in the azithromycin group compared to placebo (95% CI:0.01,2.52, p=0.046). No significant differences were seen in microbiologic, clinical, or safety endpoints.

Authors' conclusions

Azithromycin was associated with a significant reduction in risk of PEx and sustained improvement in weight but had no impact on microbiologic outcomes in children with early Pa.

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See also

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Keywords

Adolescent; Child; Anti-Bacterial Agents; Azithromycin; Bacterial Infections; 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; Tobramycin; Aminoglycosides;