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

Code: PM29890086   Year: 2018   Date:   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.

[http://dx.doi.org/10.1164/rccm.201802-0215OC](http://dx.doi.org/10.1164/rccm.201802-0215OC)

**See also**


**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;