primary studies - published RCT

Tobramycin inhalation powder in cystic fibrosis patients: Response by age group.

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

Post hoc analysis from the "Establish a New Gold Standard for Efficacy and Safety With Tobramycin in Cystic Fibrosis" (EAGER) trial, a randomized, 24-week, multicenter, open-label, parallel-group study designed to evaluate the safety of TIP versus TIS in 553 subjects, ages > 6 years, with CF and P. aeruginosa infection.

Participants

EAGER trial: 553 subjects, ages > 6 years, with CF and P. aeruginosa infection. This post hoc analysis was undertaken in 517 subjects who took > 1 dose of study medication, to evaluate the relative efficacy and safety of TIP and TIS by age group: > 6 to < 13 y (children, n = 46); > 13 to < 20 y (adolescents, n = 114); and > 20 y (adults, n = 357).

Interventions

Tobramycin powder for inhalation (TIP) vs tobramycin inhalation solution (TIS)

Outcome measures

The main efficacy end point of the EAGER trial was percent-of-predicted FEV1 at week 20 (end of third cycle of treatment). Results: Improvements in percent-of-predicted FEV1 from baseline

Main results

Improvements in percent-of-predicted FEV1 from baseline to end of cycle 3 were greatest in the children for both TIP and TIS. The treatment differences (TIP - TIS) were 4.7% (85% CI -1.2 to 10.6), 3.7% (85% CI -0.1 to 7.5), and -0.8% (85% CI -3.1 to 1.5) in children, adolescents, and adults, respectively. Sputum P. aeruginosa density decreased from baseline with both treatments, with comparable treatment differences across the age groups after 3 cycles: children -0.93 (85% CI -2.4 to 0.5), adolescents -0.17 (85% CI -1.2 to 0.8), and adults -0.89 (85% CI -1.3 to -0.4). Overall, subject satisfaction scores were greater in all subjects with TIP, irrespective of age group. With the exception of cough and dysphonia, the safety profile of TIP was comparable to TIS, irrespective of age.

Authors' conclusions

TIP is comparable to TIS in efficacy outcomes and safety profile but had greater patient satisfaction in all the age groups.

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See also

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Keywords

Anti-Bacterial Agents; Inhalation OR nebulised; pharmacological_intervention; Powders; Tobramycin; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Aminoglycosides;