primary studies - published RCT

Tobramycin inhalation powder manufactured by improved process in cystic fibrosis: the randomized EDIT trial.

Code: PM23672633 **Year:** 2013 **Date:** 2013 **Author:** Galeva I

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

Double-blind, randomized multicenter trial.

Participants

CF subjects aged 6-21 years with a forced expiratory volume in 1 second (FEV1) >/=25% to

Interventions

Patients were randomized to receive TIP or placebo (1:1) twice daily for one treatment cycle (28.5 days on drug, 28 days off drug).

Outcome measures

The primary endpoint was relative change in forced expiratory volume in 1 second (FEV1) % predicted from baseline to Day 29. A pre-specified sensitivity analysis evaluated absolute change in FEV1 % predicted. Other endpoints included Pa sputum density and safety.

Main results

A total of 62 patients out of a target of 100 (mean age 12.9 years, baseline FEV1 59.2% predicted, Pa sputum density 7.4 log10 colony forming units [CFU]) per gram were randomized. Mean treatment differences (TIP-placebo) were 5.9% (p=0.148) and 4.4% (p

Authors' conclusions

Relative change in FEV1 % predicted with TIP treatment was in the expected range based on the literature, but did not reach statistical significance versus placebo. Placebo control and use of treatment naive patients led to significant recruitment challenges and an underpowered study with consequent impact on the generated data. However, significant improvements in other outcomes including absolute change in FEV1 % predicted and reduction in Pa sputum density indicate that TIP is efficacious and well tolerated in CF patients.

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See also

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Keywords

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