primary studies - published RCT

One-year safety and efficacy of tobramycin powder for inhalation in patients with cystic fibrosis.

Code: PM26709158 **Year:** 2016 **Date:** 2016 **Author:** Konstan MW

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

Integrated analysis of data

Participants

Patients with cystic fibrosis (CF) aged 6-21 years who were treated with up to seven cycles of tobramycin powder for inhalation (TIP(TM)) over a period of at least 1 year.

Interventions

Patients treated with up to seven cycles of tobramycin powder for inhalation (TIP(TM)) over a period of at least 1 year.

Outcome measures

Safety and key efficacy endpoints were analyzed.

Main results

The improvement in lung function and decrease in sputum P. aeruginosa (Pa) density from baseline were sustained over the 1-year treatment period. The number of adverse events (AEs) was low and did not increase with additional cycles of TIP treatment. Some increase in tobramycin minimum inhibitory concentration (MIC) was observed, but there was no significant increase in emergence of resistant strains based on the parenteral breakpoint for tobramycin.

Authors' conclusions

Efficacy of TIP was maintained for up to seven cycles. Long-term treatment with TIP was generally safe and well tolerated with no increase in AEs.

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See also

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Keywords

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