

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.

http://dx.doi.org/10.1002/ppul.23358

## See also

Pediatr Pulmonol. 2016 Apr;51(4):372-8. doi: 10.1002/ppul.23358. Epub 2015 Dec 27.

# Keywords

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