

primary studies - published RCT

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

**Code:** PM23983274    **Year:** 2014    **Date:** 2018

**Author:** Geller DE

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

Multicenter, randomized, prospective study

### **Participants**

People with CF and their caregivers.

### **Interventions**

Study comparing the efficacy and safety of different durations of IV antibiotics for Pulmonary exacerbations (PEX)

### **Outcome measures**

Forced expiratory volume in 1s (FEV1% predicted) and symptom responses at 7-10days

### **Main results**

IV antibiotic duration was cited as the most important PEX research question by responding CF physicians and top concern among surveyed CF patients/caregivers. During PEX, forced expiratory volume in 1s (FEV1% predicted) and symptom responses at 7-10days of IV antibiotics identified two distinct groups: early robust responders (ERR) who subsequently experienced greater FEV1 improvements compared to non-ERR (NERR). In addition to greater FEV1 and symptom responses, only 14% of ERR patients were treated with IV antibiotics for >15days, compared with 45% of NERR patients.

### **Authors' conclusions**

A divergent trial design that evaluates subjects' interim improvement in FEV1 and symptoms to tailor randomization to IV treatment duration (10 vs. 14days for ERR, 14 vs. 21days for NERR) may alleviate physician and patient concerns about excess or inadequate treatment. Such a study has the potential to provide evidence necessary to standardize IV antibiotic duration in CF PEX care -a first step to conducting PEX research of other treatment features.

<http://dx.doi.org/10.4187/respcare.02264>.

### **See also**

Respir Care. 2014 Mar;59(3):388-98.

### **Keywords**

Exacerbation; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections; Anti-Bacterial Agents; pharmacological\_intervention; Intravenous;