

primary studies - published RCT

## **Safety, efficacy and convenience of colistimethate sodium dry powder for inhalation (Colobreathe DPI) in patients with cystic fibrosis: a randomised study.**

**Code:** PM23135343

**Year:** 2013 **Date:** 2016

**Author:** Schuster A

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

Double-blind trial

### **Participants**

Cystic fibrosis patients with chronic pseudomonal respiratory infections

### **Interventions**

Continuous alternating therapy (CAT) vs an intermittent treatment regimen. Subjects were treated with 3cycles of 28-days inhaled aztreonam (AZLI) or placebo 3-times daily alternating with 28-days open-label tobramycin inhalation solution (TIS). 90 subjects were randomized over 18months.

### **Outcome measures**

Exacerbation rates and rates of respiratory hospitalizations

### **Main results**

90 subjects were randomized over 18months. Study enrollment was limited, in part because of evolving practices by clinicians of adopting a CAT regimen in clinical practice; consequently the study was underpowered. AZLI/TIS treatment reduced exacerbation rates by 25.7% ( $p=0.25$ ; primary endpoint) and rates of respiratory hospitalizations by 35.8% compared with placebo/TIS ( $p=0.14$ ). AZLI/TIS CAT therapy was well tolerated.

### **Authors' conclusions**

This trial illustrates challenges with studying treatment regimens in a constantly evolving CF care environment. Nonetheless, the results of this trial indicate that AZLI/TIS CAT is well tolerated and may provide additional clinical benefit in CF patients compared with intermittent use of TIS alone.

<http://dx.doi.org/10.1136/thoraxjnl-2012-202059>

### **See also**

Thorax. 2013 Apr;68(4):344-50. doi: 10.1136/thoraxjnl-2012-202059. Epub 2012 Nov 7.

### **Keywords**

Adult; Aged; Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Child; Infection; Inhalation OR nebulised; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Monobactams; Aminoglycosides;