

*primary studies - published RCT*

## **Controlled trial of cycled antibiotic prophylaxis to prevent initial *Pseudomonas aeruginosa* infection in children with cystic fibrosis.**

**Code:** PM20729233

**Year:** 2010 **Date:** 2010

**Author:** Tramper-Stranders GA

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

3-year triple-blind randomised controlled trial

### **Participants**

65 children with CF without *P aeruginosa* infection.

### **Interventions**

Intervention consisted of 3-monthly 3-week treatments with oral ciprofloxacin and inhaled colistin or both placebo controls.

### **Outcome measures**

The primary outcome was *P aeruginosa* infection. Secondary outcomes were serum anti-*Pseudomonas* antibodies, pulmonary function, exacerbations, chest x-ray scores, inflammation parameters, respiratory pathogens and antimicrobial resistance.

### **Main results**

There was no difference in acquisition of *P aeruginosa* infection between the control and treatment groups (annual incidence 14% vs 11%; HR 0.738, 95% CI 0.299 to 1.822). Anti-*Pseudomonas* antibodies emerged earlier in the control group, but this difference had disappeared after 3 years. Chronic infection was observed in 19% of controls and 12% of treated patients. Decline in pulmonary function and other clinical outcomes did not differ between the two groups. In the treatment group, significantly fewer Gram-positive bacteria and Enterobacteriaceae were observed but there were more non-*P aeruginosa* non-fermentative Gram-negative bacteria.

### **Authors' conclusions**

Three-monthly cycled anti-*P aeruginosa* prophylaxis does not reduce the risk of initial and chronic infection in *P aeruginosa*-negative children with CF of all ages. Shifts in bacterial colonisation demand caution.

<http://dx.doi.org/10.1136/thx.2009.126128>

### **See also**

Thorax. 2010 Oct;65(10):915-20. Epub 2010 Aug 20.

### **Keywords**

Adolescent; Anti-Bacterial Agents; Bacterial Infections; Child; Infant; Infection; Newborn; pharmacological\_intervention; prevention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Inhalation OR nebulised; Oral; Ciprofloxacin; Colistin; Quinolones; other anti-bacterial agents;