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 existed 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;