

primary studies - published RCT

## **Effectiveness of a new enteric coated (EC) pancreatic enzyme with bicarbonate (pancrecarb®) in reducing steatorrhea in patients with cystic fibrosis (CF): a prospective randomized study.**

**Code:** CN-00404022    **Year:** 1998    **Date:** 2002

**Author:** Brady MS

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

Randomised placebo controlled cross-over trial.

### **Participants**

41 CF children (8 to 18 years).

### **Interventions**

Azithromycin, 250 mg (500 mg if weight > 40 kg) once a day for 6 months versus placebo.

### **Outcome measures**

% change in FEV1 (average of 4 and 6 month values, also for FVC and MEF), hearing, sputum bacterial densities, inflammatory markers, exercise tolerance, subjective well-being.

### **Main results**

Median relative difference in FEV1 between azithromycin and placebo was 5.4% (95% CI 0.8-10.5). 13 of 41 patients improved by more than 13% and five of 41 deteriorated by more than 13% ( $p=0.059$ ). Forced vital capacity and mid-expiratory flow did not significantly change overall. 17 of 41 patients had 24 fewer oral antibiotic courses when on azithromycin than when taking placebo, and five had six extra courses ( $p=0.005$ ). Sputum bacterial densities, inflammatory markers, exercise tolerance, and subjective well-being did not change. There were no noticeable side-effects

### **Authors' conclusions**

A 4-6-month trial of azithromycin is justified in children with cystic fibrosis who do not respond to conventional treatment. The mechanism of action remains unknown.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/022/CN-00404022/frame.html>

### **See also**

Pediatric Pulmonology YR: 1998 VL: Suppl 17 DE: RCT

### **Keywords**

Adolescent; Anti-Bacterial Agents; Anti-Inflammatory Agents; Azithromycin; Child; pharmacological\_intervention; placebo; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Macrolides; Anti-Inflammatory Agents - excl Steroids;