

primary studies - published RCT

## **Controlled trial of inhaled budesonide in patients with cystic fibrosis and chronic bronchopulmonary *Pseudomonas aeruginosa* infection.**

**Code:** PM9351621

**Year:** 1997 **Date:** 2002

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

Randomised placebo-controlled trial.

### **Participants**

60 CF adult participants. Mean age 27.9 (SD, 6.5). The placebo group contained more men (20/30 versus 9/30), was taller, heavier and had better lung function (FEV1 mean (SD), 62.3 (24.8) versus 50.9 (18.3)).

### **Interventions**

Azithromycin, 250 mg once a day for 3 months versus placebo.

### **Outcome measures**

% change in FEV1 (FVC), weight, QoL, inflammatory markers, microbiology, respiratory exacerbations.

### **Main results**

Sixty patients were recruited (29 men) of mean (SD) age 27.9 (6.5) years and initial forced expiratory volume in 1 second (FEV1) 56.6 (22.3)% predicted. FEV1% and forced vital capacity (FVC)% predicted were maintained in the AZM group while in the placebo group there was a mean (SE) decline of -3.62 (1.78)% (p=0.047) and -5.73 (1.66)% (p=0.001), respectively. Fewer courses of intravenous antibiotics were used in patients on AZM (0.37 v 1.13, p=0.016). Median C reactive protein (CRP) levels declined in the AZM group from 10 to 5.4 mg/ml but remained constant in the placebo group (p

### **Authors' conclusions**

AZM in adults with CF significantly improved QOL, reduced CRP levels and the number of respiratory exacerbations, and reduced the rate of decline in lung function. Long term AZM may have a significant impact on morbidity and mortality in patients with CF. Further studies are required to define frequency of dosing and duration of benefit.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/704/CN-00144704/frame.html>

### **See also**

Am J Respir Crit Care Med. 1997 Oct;156(4 Pt 1):1190-6.

### **Keywords**

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