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primary studies - published RCT

## Long term azithromycin in children with cystic fibrosis: a randomised, placebo-controlled crossover trial.

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### 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://dx.doi.org/10.1016/S0140-6736\(02\)11081-6](http://dx.doi.org/10.1016/S0140-6736(02)11081-6)

### See also

Lancet. 2002 Sep 28;360(9338):978-84.

### 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;