primary studies - published RCT

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

Code: PM12383667 **Year:** 2002 **Date:** 2002 **Author:** Equi A

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.

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See also

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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;