

primary studies - published RCT

## Treatment of *Aspergillus fumigatus* in patients with cystic fibrosis: a randomized, placebo-controlled pilot study.

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

double-blind randomized placebo-controlled pilot clinical

### Participants

35 patients with CF whose sputum cultures were chronically positive for *A. fumigatus*.

### Interventions

Participants were centrally randomized to receive either oral itraconazole 5 mg/kg/d (N = 18) or placebo (N = 17) for 24 weeks.

### Outcome measures

The primary outcome was the proportion of patients who experienced a respiratory exacerbation requiring intravenous antibiotics over the 24 week treatment period. Secondary outcomes included changes in FEV(1) and quality of life.

### Main results

Over the 24 week treatment period, 4 of 18 (22%) patients randomized to itraconazole experienced a respiratory exacerbation requiring intravenous antibiotics, compared to 5 of 16 (31%) placebo treated patients,  $P = 0.70$ . FEV(1) declined by 4.62% over 24 weeks in the patients randomized to itraconazole, compared to a 0.32% improvement in the placebo group (between group difference = -4.94%, 95% CI: -15.33 to 5.45,  $P = 0.34$ ). Quality of life did not differ between the 2 treatment groups throughout the study. Therapeutic itraconazole blood levels were not achieved in 43% of patients randomized to itraconazole.

### Authors' conclusions

We did not identify clinical benefit from itraconazole treatment for CF patients whose sputum was chronically colonized with *A. fumigatus*. Limitations of this pilot study were its small sample size, and failure to achieve therapeutic levels of itraconazole in many patients.

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### See also

PLoS One. 2012;7(4):e36077. Epub 2012 Apr 30.

### Keywords

Adult; Aged; *Aspergillus*; Child; Fungi; Infection; Itraconazole; pharmacological\_intervention; Antifungal Agents; Respiratory Tract Diseases; Respiratory Tract Infections;