primary studies - published RCT

Long-term clarithromycin in cystic fibrosis: effects on inflammatory markers in BAL and clinical status.

Code: PM20112595 **Year:** 2009 **Date:** 2012 **Author:** Dogru D

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.

http://www.ncbi.nlm.nih.gov/pubmed/20112595

See also

Turk J Pediatr. 2009 Sep-Oct;51(5):416-23.

Keywords

Adult; Aged; Aspergillus; Child; Fungi; Infection; Itraconazole; pharmacological_intervention; Antifungal Agents; Respiratory Tract Diseases; Respiratory Tract Infections;