primary studies - published RCT

Effect of esomeprazole versus placebo on pulmonary exacerbations in cystic fibrosis.

Code: PM24528942 **Year:** 2014 **Date:** 2014 **Author:** DiMango E

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

Randomized controlled study

Participants

Patients with CF and frequent respiratory exacerbations. 17 patients without symptoms of GER were randomized and 15 completed the study.

Interventions

Esomeprazole 40 mg twice daily versus placebo over a thirty-six week treatment period

Outcome measures

Time to first exacerbation; Forced Expiratory Volume in one second; Gastroesophageal Symptom Assessment Score or CF Quality of Life.

Main results

17 patients without symptoms of GER were randomized and 15 completed the study. 13 subjects underwent 24 hour ambulatory pH probe monitoring; 62% had pH probe evidence of GER. Forty one percent of subjects had a pulmonary exacerbation during the study. There was no significant difference in time to first pulmonary exacerbation (log rank test p = 0.3169). Five of nine subjects in the esomeprazole group compared with 2 of eight subjects in the placebo group experienced exacerbations (esomeprazole vs. placebo: odds ratio = 3.455, 95% CI = (0.337, 54.294), Fisher's exact test: p = 0.334). There was no change in Forced Expiratory Volume in one second, Gastroesophageal Symptom Assessment Score or CF Quality of Life score between the two treatment groups.

Authors' conclusions

There was a trend to earlier exacerbation and more frequent exacerbations in subjects randomized to esomeprazole compared with placebo. The effect of proton pump inhibitors on pulmonary exacerbations in CF warrants further investigation.

http://dx.doi.org/10.1186/1471-2466-14-21.

See also

BMC Pulm Med. 2014 Feb 15;14:21.

Keywords

Adult; Gastrointestinal Agents; pharmacological_intervention; Omeprazole; Proton pump inhibitors;