primary studies - published RCT

Ranitidine and omeprazole as adjuvant therapy to pancrelipase to improve fat absorption in patients with cystic fibrosis.

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

double-blind, placebo-controlled crossover study

Participants

12 children and 10 adults with pancreatic insufficient CF.

Interventions

All subjects were receiving pancrelipase therapy (Pancrease MT10 and MT16; Ortho-McNeil, Springhouse, PA, U.S.A.) and for the study also received either placebo or ranitidine (Zantac; Glaxo-Wellcome, Research Triangle Park, NC U.S.A.) 5 mg/kg or 10 mg/kg daily. The adult subjects also received omeprazole therapy (Prilosec; AstraZeneca/Merck, Wilmington, DE, U.S.A.), 20 mg daily, as adjuvant therapy to pancreatic enzymes.

Outcome measures

Serial 3-day fat-balance studies were performed in the Clinical Research Center. The data were analyzed using individual paired t tests that compared each treatment with placebo and two repeated-measures, general linear model F tests.

Main results

The linear model for all subjects showed no overall adjuvant drug effect on fat absorption, P = 0.32. A second linear model F test analysis of adult subjects, comparing all four drug treatments (placebo, ranitidine 5 and 10 mg/kg daily and omeprazole), also showed no difference in fat absorption, P = 0.15. Paired t test subgroup analysis of the adults showed an improvement of 4.97% (P = 0.003) in mean fat absorption comparing low-dose ranitidine to placebo. All other t test analyses showed no significant change in fat absorption between placebo and acid suppressant treatment. There was marked intersubject and intrasubject variability in fat absorption.

Authors' conclusions

No overall significant improvement in fat absorption could be demonstrated with adjuvant therapy. Fat absorption measured by 3-day fat-balance studies varied greatly even when comparing the same subject for placebo and baseline treatments, despite identical dietary fat and enzyme intakes. The large variability limited our ability to test for a difference in fat absorption and has significant implication for the use of this test, considered the gold standard, for determining enzyme dosage adequacy.

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See also

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Keywords

Adolescent; Adult; Child; Gastrointestinal Agents; non pharmacological intervention - diet; Omeprazole; Pancreatic Enzyme Replacement Therapy; pharmacological_intervention; placebo; Ranitidine; Supplementation; Pancreas insufficiency; Pancreatic Diseases; Gastrointestinal Diseases; Malabsorption; Nutrition Disorders; Proton pump inhibitors; Histamine H2 Antagonists; Pancrelipase;