primary studies - published RCT

An enteric-coated high-buffered pancrelipase reduces steatorrhea in patients with cystic fibrosis: a prospective, randomized study.

Code: PM16863712 **Year:** 2006 **Date:** 2006 **Author:** Brady MS

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

Prospective, randomized, controlled trial using a crossover design with each subject as his/her own control.

Participants

18 subjects with cystic fibrosis, who had pancreatic insufficiency and required large enzyme doses, were studied over two consecutive 7-day treatment periods.

Interventions

Each 7-day period consisted of 3 days at home followed by 4 days in a general clinical research center for careful control of diets, enzyme lipase doses (given at approximately 50% of the subject's usual lipase dose), and carmine red-labeled stool collections for 72-hour fecal fat balance studies.

Outcome measures

Fecal fat excretion.

Main results

Mean fat excretion decreased significantly in each subject during periods when given EC-high-buffered pancrelipase compared with periods when given EC-nonbuffered enzymes (fat excretion 18.2% vs 24.9% or fat absorption 81.8% vs 75.1%, respectively; P=0.01). Thirteen of 18 subjects (72%) excreted less fat when receiving EC-high-buffered pancrelipase whereas 10 (56%) decreased fat excretion by more than 5%, and five subjects did not respond.

Authors' conclusions

EC-high-buffered pancrelipase decreased fat excretion, symbolizing improved fat absorption, when compared with EC-nonbuffered pancreatic enzymes given at equivalent, reduced (approximately 50% of usual) lipase doses in nourished subjects with cystic fibrosis and mild pulmonary disease.

http://dx.doi.org/10.1016/j.jada.2006.05.011

See also

J Am Diet Assoc. 2006 Aug;106(8):1181-6.

Keywords

Adolescent; Adult; Child; Enteric-Coated; Gastrointestinal Agents; Gastrointestinal Diseases; Microspheres; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Supplementation; Malabsorption; Nutrition Disorders; Home; Pancrelipase;