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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;