

primary studies - published RCT

## **A comparison of the efficacy and tolerance of pancrelipase and placebo in the treatment of steatorrhea in cystic fibrosis patients with clinical exocrine pancreatic insufficiency.**

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**Author:** Stern RC

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

open-label phase + double-blind phase.

### **Participants**

97 CF patients with pancreatic insufficiency and steatorrhea (open-label phase); 74 patients with >80% coefficient of fat absorption (double-blind phase)

### **Interventions**

In the double-blind phase patients were stabilized on a high-fat diet and administered pancrelipase. In the open-label phase patients received placebo or pancrelipase.

### **Outcome measures**

Fat intake and excretion, stool frequency and consistency, and clinical global improvement were recorded.

### **Main results**

Average daily fat intake was comparable between treatment groups within each age group (adults vs pediatric/adolescent), but placebo patients had a significant ( $p < 0.001$ ) mean decrease in coefficient of fat absorption (adult, 36.9 percentage points; pediatric/adolescent, 34.9 percentage points) from open-label to double-blind treatment compared to pancrelipase patients (adult, 2 percentage points; pediatric/adolescent, 3.25 percentage points); this difference was caused by a greater ( $p < \text{or} = 0.001$ ) increase in mean fecal fat excretion (grams per day) in the placebo groups compared to pancrelipase groups (adult: 61.9 vs 2.3; pediatric/adolescent: 45.4 vs 4.1). Change in mean stool frequency from open-label to double-blind phases was significantly different ( $p < \text{or} = 0.002$ ) between treatment groups, with increases in placebo groups and no difference (adult) or decrease (pediatric/adolescent) in pancrelipase groups. Pancrelipase patients' stool consistency remained about the same from open-label to double-blind. Placebo patients' stool consistency decreased (became softer) from open-label pancrelipase to double-blind placebo. Clinical global improvement data showed that  $> \text{or} = 83\%$  of pancrelipase patients improved or remained unchanged.

### **Authors' conclusions**

Enteric-coated, delayed-release (Minimicrospheres) pancrelipase capsules are an effective treatment for steatorrhea associated with pancreatic insufficiency in patients with cystic fibrosis.

<http://dx.doi.org/10.1111/j.1572-0241.2000.02244.x>

### **See also**

Am J Gastroenterol. 2000 Aug;95(8):1932-8.

### **Keywords**

Adult; Gastrointestinal Agents; Gastrointestinal Diseases; pharmacological\_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; placebo; Malabsorption; Nutrition Disorders; Pancrelipase;