

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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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.

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See also

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Keywords

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