

primary studies - published RCT

A prospective randomized trial of early diagnosis and treatment of cystic fibrosis: a unique ethical dilemma.

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Author: Fost N

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

randomized double-blind crossover study

Participants

13 cystic-fibrosis patients (6 males, 7 females, mean age 27.7 years)

Interventions

four capsules of Pancrease t.d.s. or one capsule of Pancrease-HL t.d.s. Patients took 20 mg omeprazole daily to raise intra-duodenal pH and thus optimize release of enzymes from the enteric coated microspheres.

Outcome measures

fat excretion, nitrogen excretion, fat and protein energy loss, pancrease-HL tolerance, abdominal pain, general well-being scores, number and average weight of stools

Main results

With four capsules of Pancrease t.d.s., mean fat excretion was 15.4% and mean nitrogen excretion was 19.9% vs. 15.5% fat and 19.9% nitrogen excretion with one capsule Pancrease-HL t.d.s. Fat and protein energy loss (as a percentage of total daily intake) was 18.3% with Pancrease and 18.2% with Pancrease-HL. The differences were not statistically significant. Pancrease-HL was well tolerated, with no difference in abdominal pain or general well-being scores. The number and average weight of stools passed remained the same.

Authors' conclusions

One capsule of Pancrease-HL appears to be equivalent to four capsules of regular Pancrease. Treatment with less capsules per day with the same efficacy may facilitate patient compliance.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/337/CN-00062337/frame.html>

See also

Clin Res. 1989 Sep;37(3):495-500.

Keywords

Adult; Gastrointestinal Agents; Omeprazole; Pancreatic Enzyme Replacement Therapy; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Gastrointestinal Diseases; Malabsorption; Nutrition Disorders; Capsules; Enteric-Coated; Microspheres; Proton pump inhibitors;