primary studies - published RCT

High- versus low-lipase acid-resistant enzyme preparations in cystic fibrosis: a crossover randomized clinical trial.

Code: PM8788291 **Year:** 1996 **Date:** 1996 **Author:** Lancellotti L

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

randomized crossover study

Participants

20 adolescent or adult cystic fibrosis patients

Interventions

patients were treated in hospital with both low-lipase (A) and high-lipase (B) enteric-coated microsphere preparations. With both preparations, patients were given a daily dose of 1,500-2,000 lipase BP U/g fat ingested, distributed across four meals. The low-strength preparation was divided into three doses during each meal, while the high-strength preparation was taken as a single dose in the middle of each meal.

Outcome measures

The fat excretion coefficient, evaluated over two 72-h fat balance periods (measured fat intake, 1.43 to 3 g/kg/day according to age), was the main response variable, secondary variables being stool wet and dry weight, fecal nitrogen output, and energy loss.

Authors' conclusions

The considerable variability of results did not provide conclusive evidence of equivalence or significant differences between the two preparations in terms of steatorrhea and other variables. However, mean differences between the two treatments and their 95% confidence intervals showed less satisfactory results with the high-lipase preparation. A high-strength preparation is thought to release relatively less enzyme activity in the small intestine, forcing patients to increase their dosage and possibly creating a dangerous enzyme hyperconcentration in the large intestine. For this reason, the occasional occurrence of colonic stricture should be borne in mind, as must the possible scope for division of dosage during each meal.

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See also

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Keywords

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