primary studies - published RCT

Efficacy and tolerability of a new formulation of pancrelipase delayed-release capsules in children aged 7 to 11 years with exocrine pancreatic insufficiency and cystic fibrosis: a multicenter, randomized, double-blind, placebo-controlled, two-period crossover, superiority study.

Code: PM20171415 **Year:** 2010 **Date:** 2010 **Author:** Graff GR

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

multicenter, randomized, double-blind, placebo-controlled, 2-period crossover, superiority study

Participants

children aged 7 to 11 years with CF and EPI. N=16

Interventions

new formulation of pancrelipase delayed-release 12,000-lipase unit capsules. In each period, pancrelipase or identical placebo capsules were taken for 5 days.

Outcome measures

The primary outcome measure was the coefficient of fat absorption (CFA); secondary outcome measures were the coefficient of nitrogen absorption (CNA) and clinical symptoms. The latter were assessed based on patient-reported daily stool frequency, stool consistency (hard, formed/normal, soft, or watery), flatulence (none, mild, moderate, or severe), and abdominal pain (none, mild, moderate, or severe). Safety measures included vital signs, physical examinations, standard laboratory safety tests (hematology and biochemistry), and adverse events.

Main results

17 patients were randomized to treatment and 16 completed the study; 1 patient withdrew consent during the first treatment period and was not included in the efficacy analysis. Patients' median age was 8.0 years (range, 7-11 years); 12 patients (70.6%) were males. CFA values were significantly greater for pancrelipase compared with placebo, with least squares mean (SE) values of 82.8% (2.7%) and 47.4% (2.7%), respectively (P < 0.001). The results were similar for CNA, with mean values of 80.3% (3.2%) and 45.0% (3.2%) (P < 0.001). Pancrelipase treatment had significantly greater effects on CFA and CNA in patients with a placebo CFA <50% than in those with a placebo CFA >50% (both parameters, P

Authors' conclusions

In this study in children with EPI due to CF, the new formulation of pancrelipase delayed-release capsules was associated with improvements in CFA, CNA, stool properties, and EPI symptoms compared with placebo. Pancrelipase delayed-release capsules appeared to be well tolerated.

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See also

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Keywords

Aged; Capsules; Child; Delayed-Action Preparations; Gastrointestinal Agents; Gastrointestinal Diseases; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; placebo; Supplementation; Malabsorption;

Nutrition Disorders; Pancrelipase;