primary studies - published RCT

International phase III trial of liprotamase efficacy and safety in pancreatic-insufficient cystic fibrosis patients.

Code: PM21831726 **Year:** 2011 **Date:** 2011 **Author:** Borowitz D

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

international phase III parallel-group, randomized-withdrawal, double-blind placebo-controlled trial

Participants

CF patients with exocrine pancreatic insufficiency (EPI) 7 years and older, including nutritionally and functionally compromised individuals, underwent baseline testing for coefficients of fat and nitrogen absorption (CFA and CNA) and stool weight and frequency while off PERT. 138 subjects were randomized.

Interventions

supplementation with pancreatic enzyme replacement therapy (PERT). Liprotamase, a novel non-porcine PERT containing highly purified biotechnology-derived lipase, protease, and amylase. Patients were randomized 1:1 to one liprotamase or placebo capsule taken with 3 meals and 2 snacks per day. The dose was fixed and increases were not allowed.

Outcome measures

coefficients of fat and nitrogen absorption (CFA and CNA) and stool weight and frequency

Main results

The adjusted least squares mean (LSM) difference between the treatment and placebo groups for change in CFA was 15.1% (p=0.001) for the subgroup with baseline CFA <40%, 8.6% (p=0.006) for subjects with baseline CFA >/=40%, and 10.6% (p

Authors' conclusions

In a CF patient population reflective of that encountered in clinical practice, this trial demonstrated that liprotamase at a fixed dose of one capsule per meal or snack (5 capsules per day) was well tolerated and significantly increased fat absorption as measured by improvement in CFA, significantly increased protein absorption as measured by improvement in CNA, and significantly decreased stool weight.

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See also

J Cyst Fibros. 2011 Dec;10(6):443-52. Epub 2011 Aug 9.

Keywords

Gastrointestinal Diseases; Liprotamase; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Malabsorption; Nutrition Disorders; Gastrointestinal Agents;