primary studies - published RCT

Study of a novel pancreatic enzyme replacement therapy in pancreatic insufficient subjects with cystic fibrosis.

Code: PM17095338 **Year:** 2006 **Date:** 2006 **Author:** Borowitz D

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

randomized controlled trial

Participants

Ambulatory subjects with CF-pancreatic insufficiency (PI) (n = 117)

Interventions

Subjects were randomized to treatment with ALTU-135 containing 5000 (low), 25,000 (mid), or 100,000 (highest) units of lipase (1:1:0.15 of lipase:protease:amylase) for 28 days.

Outcome measures

The primary outcomes were change from baseline in CFA and CNA between treatments

Main results

Treatment CFA was significantly greater in the mid and highest dose groups compared with that in the low dose group (P = .0229 and P =.0041, respectively); findings were similar for CNA. Subjects with baseline CFA < or = 40% and > 40% in the 2 higher dose groups had a mean increase of 31 and 8 percentage points in CFA, respectively (P

Authors' conclusions

ALTU-135 was efficacious during the 1-month study period at the dose of 25,000 units of lipase, 25,000 units of protease, and 3750 units of amylase.

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See also

J Pediatr. 2006 Nov;149(5):658-662.

Keywords

ALTU-135; Gastrointestinal Diseases; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Malabsorption; Nutrition Disorders; Gastrointestinal Agents; Liprotamase;