primary studies - published RCT

Safety and Efficacy of a Novel Microbial Lipase in Patients with Exocrine Pancreatic Insufficiency due to Cystic Fibrosis: A Randomized Controlled Clinical Trial.

Code: PM27297209 **Year:** 2016 **Date:** 2016 **Author:** Heubi JE

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

Double-blind, randomized, placebo controlled crossover study

Participants

Adolescent and adult patients with cystic fibrosis and exocrine pancreatic insufficiency. A total of 35 patients were randomized into the study and 22 patients completed both treatment periods.

Interventions

A novel microbial lipase (NM-BL) in a liquid formulation or placebo for 1 week as replacement for the usual pancreatic enzyme formulation.

Outcome measures

The coefficient of fat absorption was evaluated as the primary endpoint. Symptoms and adverse events were evaluated as secondary endpoints.

Main results

During treatment with NM-BL, the coefficient of fat absorption was significantly greater (72.7%) compared with placebo (53.8%) with a difference between groups of 18.8% (P

Authors' conclusions

Currently available pancreatic enzyme products are limited because of the lack of liquid formulations and being largely porcine based. The novel microbial lipase NM-BL was safe and effective in this short term trial. The trial provided clinical proof-of-concept for this novel microbial lipase as a treatment for EPI in CF. A larger phase 2 dose ranging trial is warranted.

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See also

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Keywords

Child; Adult; Adolescent; Gastrointestinal Diseases; Pancreas insufficiency; Pancreatic Diseases; Malabsorption; pharmacological_intervention; NM-BL; Burlulipase; Pancreatic Enzyme Replacement Therapy; Gastrointestinal Agents;