

primary studies - published RCT

# Efficacy and safety of a unique enteric-coated bicarbonate-buffered pancreatic enzyme replacement therapy in children and adults with cystic fibrosis.

**Code:** PM25210613 **Year:** 2013 **Date:** 2013 **Author:** Konstan MW

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

Randomized, double-blind, placebo-controlled cross-over design.

#### **Participants**

Children and adults with cystic fibrosis with exocrine pancreatic insufficiency.

#### Interventions

Pancreatic enzyme replacement therapy (PERT). Enteric-coated (EC) bicarbonate-buffered PERT product (PERTZYE/PANCRECARB; Digestive Care, Inc., Bethlehem, PA, USA). Subjects were stabilized on EC-bicarbonate-buffered PERT and a high-fat diet. During two treatment periods, subjects were randomized to EC-bicarbonate-buffered PERT or placebo, followed by a 72-h stool collection employing an ingested stool dye marker.

#### **Outcome measures**

Mean coefficient of fat absorption; nitrogen absorption were observed; stool frequency and stool weight decreased. Safety

#### Main results

Mean coefficient of fat absorption with EC-bicarbonate-buffered PERT was 82.5% compared with 46.3% with the placebo (absolute difference 36.2%; p

## Authors' conclusions

EC-bicarbonate- buffered PERT is effective in treating cystic fibrosis-associated exocrine pancreatic insufficiency.

http://www.future-science.com/doi/abs/10.4155/cli.13.62?journalCode=cli

### See also

Clin Investig (Lond). 2013 Aug 1;3(8):723-729.

#### Keywords

Child; Adolescent; Adult; Antacids; Bicarbonates; Enteric-Coated; Gastrointestinal Agents; Gastrointestinal Diseases; Malabsorption; pharmacological\_intervention; Nutrition Disorders; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy;