primary studies - published RCT

Efficacy and safety of PANCREAZE(R) for treatment of exocrine pancreatic insufficiency due to cystic fibrosis.

Code: PM21632288 **Year:** 2011 **Date:** 2011 **Author:** Trapnell BC

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

randomized, placebo-controlled study

Participants

n=49

Interventions

Participants (n=49) entered an open-label, </= 14 day run-in phase, maintained a high-fat diet (100 +/- 15 g/day), and received PANCREAZE(R) (10.5 or 21). Participants with a coefficient of fat absorption (CFA)> /= 80% (n=40) were then randomized (1:1) to receive either PANCREAZE(R) or placebo during a double-blind,

Outcome measures

fat absorption, protein absorption, adverse events

Main results

PANCREAZE(R) improved fat absorption as shown by significantly lower mean +/- SD change in CFA between open-label and double-blind phases for PANCREAZE(R) (-1.5 +/- 5.88%; p

Authors' conclusions

This study demonstrated PANCREAZE(R) was effective in treating EPI due to CF and was safe and well tolerated.

http://dx.doi.org/10.1016/j.jcf.2011.04.005

See also

J Cyst Fibros. 2011 Sep;10(5):350-6. Epub 2011 May 31.

Keywords

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