primary studies - published RCT

Efficacy and safety of Creon 24,000 in subjects with exocrine pancreatic insufficiency due to cystic fibrosis.

Code: PM19815466 **Year:** 2009 **Date:** 2009 **Author:** Trapnell BC

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

This was a double-blind, randomised, placebo-controlled, two-period crossover study

Participants

subjects > or =12 years with EPI. N=32

Interventions

Patients were randomised to one of two 5-day sequences, Creon/placebo or placebo/Creon (target dose, 4000 lipase units/g fat)

Outcome measures

Primary outcome was the coefficient of fat absorption (CFA); secondary outcomes were coefficient of nitrogen absorption (CNA), symptoms, and safety.

Main results

32 subjects were randomised. Mean CFA and CNA were significantly greater with Creon than placebo (CFA, 88.6% vs. 49.6%; CNA, 85.1% vs. 49.9%; p

Authors' conclusions

This study demonstrated Creon was effective in treating EPI due to CF and was safe and well tolerated.

http://dx.doi.org/10.1016/j.jcf.2009.08.008

See also

J Cyst Fibros. 2009 Dec;8(6):370-7. Epub 2009 Oct 7.

Keywords

Adolescent; Adult; Child; Creon; Gastrointestinal Agents; Gastrointestinal Diseases; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; placebo; Supplementation; Malabsorption; Nutrition Disorders;