

primary studies - published RCT

## **A multicenter, randomized, double-blind, placebo-controlled trial to evaluate the metabolic and respiratory effects of growth hormone in children with cystic fibrosis.**

**Code:** PM17545356

**Year:** 2007 **Date:** 2011

**Author:** Schnabel D

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

randomized, placebo-controlled study

### **Participants**

n=49

### **Interventions**

Participants (n=49) entered an open-label,  $\leq$  14 day run-in phase, maintained a high-fat diet (100  $\pm$  15 g/day), and received PANCREAZE(R) (10.5 or 21). Participants with a coefficient of fat absorption (CFA) $\geq$  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  $\pm$  SD change in CFA between open-label and double-blind phases for PANCREAZE(R) (-1.5  $\pm$  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/10.1542/peds.2006-2783>

### **See also**

Pediatrics. 2007 Jun;119(6):e1230-8.

### **Keywords**

Gastrointestinal Agents; Gastrointestinal Diseases; pharmacological\_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Supplementation; Malabsorption; Nutrition Disorders;