

primary studies - published RCT

## **Oral magnesium supplementation in children with cystic fibrosis improves clinical and functional variables: a double-blind, randomized, placebo-controlled crossover trial.**

**Code:** PM22648717

**Year:** 2012 **Date:** 2016

**Author:** Gontijo-Amaral C

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

Randomised, double-blind, crossover, multinational, multicentre non-inferiority study

### **Participants**

96 Patients on a standardised diet and stabilised treatment (mean age 19.2years, 60.4% males)

### **Interventions**

Zenpep and Kreon, both containing 25,000 lipase units, were compared. Patients on a standardised diet and stabilised treatment were randomised to two treatment sequences: Zenpep/Kreon or Kreon/Zenpep.

### **Outcome measures**

The primary efficacy endpoint was the coefficient of fat absorption over 72h (CFA-72h).

### **Main results**

83 patients completed both sequences comprising the efficacy population. Zenpep demonstrated non-inferiority and equivalence to Kreon in fat absorption (LS mean CFA-72h: Zenpep, 84.1% [SE 1.1] vs. Kreon, 85.3% [SE 1.1];  $p=0.297$ ). Safety and tolerability were similar.

### **Authors' conclusions**

Zenpep is comparable with Kreon in efficacy and safety for the treatment of adolescents and adults with CF-associated EPI.

<http://dx.doi.org/10.3945/ajcn.112.034207>

### **See also**

Am J Clin Nutr. 2012 Jul;96(1):50-6. Epub 2012 May 30.

### **Keywords**

Adolescent; Adult; Child; Enteric-Coated; Gastrointestinal Diseases; Malabsorption; pharmacological\_intervention; Nutrition Disorders; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; EUR-1008; Gastrointestinal Agents; Creon;