primary studies - published RCT

Comparison of two pancreatic enzyme products for exocrine insufficiency in patients with cystic fibrosis.

Code: PM27013382 **Year:** 2016 **Date:** 2016 **Author:** Taylor CJ

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.

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See also

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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;