primary studies - published RCT

Pancreatic enzyme replacement therapy for young cystic fibrosis patients.

Code: PM18718819 **Year:** 2009 **Date:** 2009 **Author:** Munck A

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

prospective, randomised, cross-over, multi-centre study

Participants

40 infants and toddlers with CF

Interventions

Creon for children (CfC) and Creon 10000 (C10) for two weeks each in a cross-over design.

Outcome measures

Dosing of pancreatic enzymes was continued as applied before the study. The primary endpoint was the parents' treatment preference. Secondary endpoints included coefficient of fat absorption (CFA), clinical symptoms and safety parameters

Main results

20 parents (51%) from the N=39 intent to treat sample preferred CfC, 9 (23%) preferred C10, and 10 (26%) had no preference The applied doses led to a mean CFA with similar results for both treatments (77.8% vs. 78.7%). Gastrointestinal symptoms were reported on a number of study days, and some children had abnormal results for laboratory parameters of malabsorption. Safety and tolerability of the preparations were good and all these parameters were comparable for both treatments.

Authors' conclusions

Those parents who had a preference favoured CfC over C10. Both enzyme preparations improved malabsorption to a similar degree, although the applied dosages could have been too low in some children reflected in a suboptimal CFA. These data support the use of CfC for young patients with cystic fibrosis improving the daily care of this cohort detected mainly now through neonatal screening programmes.

http://dx.doi.org/10.1016/j.jcf.2008.07.003

See also

J Cyst Fibros. 2009 Jan;8(1):14-8. Epub 2008 Aug 21.

Keywords

Child; Gastrointestinal Agents; Infant; Microspheres; Oral; Pancreatic Enzyme Replacement Therapy; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Gastrointestinal Diseases; Malabsorption; Nutrition Disorders; Creon;