primary studies - published RCT

Ultrase MT12 and Ultrase MT20 in the treatment of exocrine pancreatic insufficiency in cystic fibrosis: safety and efficacy.

Code: PM15606399 **Year:** 2004 **Date:** 2004 **Author:** Konstan MW

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

RCT

Interventions

Ultrase MT12 (12,000 lipase units per capsule) and Ultrase MT20 (20,000 lipase units per capsule), to placebo in two separate safety and efficacy studies.

Outcome measures

total fat, protein and carbohydrate intake, fat and protein absorption, adverse events

Main results

Mean total fat, protein and carbohydrate intake did not differ significantly between the groups. A significant difference in both fat and protein absorption occurred with the enzyme therapy groups. The Ultrase MT12 and Ultrase MT20 groups experienced a mean fat and protein absorption 79.4% and 83.8%, and 87.3% and 88.6%, respectively. No adverse events related to study drug were reported.

Authors' conclusions

This study further supports the use of enzymes to treat pancreatic insufficiency in cystic fibrosis. Excellent fat and protein absorption was achieved with minimal adverse events and safe doses.

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See also

Aliment Pharmacol Ther. 2004 Dec;20(11-12):1365-71.

Keywords

Adolescent; Adult; Aged; Child; Gastrointestinal Agents; Gastrointestinal Diseases; pharmacological_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Malabsorption; Nutrition Disorders; Capsules; ULTRASE;