

primary studies - published RCT

A double-blind placebo controlled trial with oral ambroxol and N-acetylcysteine for mucolytic treatment in cystic fibrosis.

Code: PM3908111

Year: 1985 **Date:** 1992

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

study 1: randomized trial study 2: open randomised crossover fat-balance study

Participants

10 adult patients with pancreatic steatorrhea due to cystic fibrosis (CF)

Interventions

study 1: acid-resistant fungal lipase prepared from *Aspergillus niger* or placebo by mouth. study 2: conventional pancreatin microsphere formulations. Each preparation was given for 2 weeks, and a fat-balance study, using a faecal recovery marker, was performed on the final 3 days; a period without treatment was also included.

Outcome measures

study1: gastric contents for the following 2 h study 2: faecal wet weight, fat absorption

Main results

study 1: Mean acid-resistant lipase activity was 330 nmol/ml/min free fatty acid released on placebo, compared with 896 nmol/ml/min on fungal lipase ($p = 0.006$ for area under the curve). study 2: The fungal lipase had no effect on faecal wet weight or on the coefficient of fat absorption (59.0% vs. 52.3%; NS) in comparison with placebo. The established enteric-coated microsphere preparation (Creon) produced a significant reduction in faecal wet weight and improvement in coefficient of fat absorption (81.4% vs. 52.3%; p less than 0.01) in comparison with placebo. The newer microsphere preparation (Pancrex M) was also effective, but perhaps less so than Creon; there were no significant differences between the two preparations.

<http://dx.doi.org/10.1007/BF00441781>

See also

Eur J Pediatr. 1985 Nov;144(4):374-8.

Keywords

Adult; Fungi; Gastrointestinal Diseases; Infection; pharmacological_intervention; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Supplementation; Pancreas insufficiency; Antifungal Agents; Malabsorption; Nutrition Disorders; Microspheres; Gastrointestinal Agents;