

Cochrane Database of Systematic Reviews - - Cochrane Review

# Pancreatic enzyme replacement therapy for people with cystic fibrosis

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

Randomised controlled trials and quasi-randomised controlled trials

#### List of included studies (14)

Assoufi 1994; Borowitz 2005; Elliott 1992; Henker 1987; Lacy 1992; Patchell 1999; Petersen 1984; Stead 1986; Stead 1987; Taylor 2015; Vidailhet 1987; Vyas 1990; Williams 1990

#### **Participants**

People with CF

# Interventions

Pancreatic enzyme replacement therapy, at any dosage and in any formulations, in both the home and hospital setting, for a period of not less than four weeks, compared either to placebo or other PERT preparations, commenced either at diagnosis of cystic fibrosis, at the onset of symptoms or at confirmation of abnormal pancreatic function

#### **Outcome measures**

Primary outcomes: changes in nutritional status (weight, height, BMI Z scores).

# Main results

14 trials were included in the review (641 children and adults with CF), two of these were parallel trials and 12 were cross―over trials. Interventions included different enteric and non―enteric―coated preparations of varying formulations in comparison to each other. The number of participants in each trial varied between 14 and 129. 13 trials were for a duration of four weeks and one trial lasted seven weeks. The majority of the trials had an unclear risk of bias from the randomisation process as the details of this were not given; they also had a high risk of attrition bias and reporting bias. The quality of the evidence ranged from moderate to very low. We mostly could not combine data from the trials as they compared different formulations and the findings from individual trials provided insufficient evidence to determine the size and precision of the effects of different formulations.

# Authors' conclusions

There is limited evidence of benefit from enteric―coated microspheres when compared to non―enteric coated pancreatic enzyme preparations up to one month. In the only comparison where we could combine any data, the fact that these were cross―over trials is likely to underestimate the level of inconsistency between the results of the trials due to over―inflation of Cls from the individual trials. There is no evidence on the long―term effectiveness and risks associated with PERT. There is also no evidence on the relative dosages of enzymes needed for people with different levels of severity of pancreatic insufficiency, optimum time to start treatment and variations based on differences in meals and meal sizes. There is a need for a properly designed trial that can answer these questions.

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#### See also

Somaraju URR, Solis-Moya A. Pancreatic enzyme replacement therapy for people with cystic fibrosis. Cochrane Database of Systematic Reviews 2020, Issue 8. Art. No.: CD008227. DOI: 10.1002/14651858.CD008227.pub4.

#### Keywords

Gastrointestinal Diseases; pharmacological\_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme



Replacement Therapy; Malabsorption; Nutrition Disorders; Gastrointestinal Agents;