

Cochrane Database of Systematic Reviews - - Cochrane Review

# Timing of pancreatic enzyme replacement therapy (PERT) in cystic fibrosis

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

Randomised controlled trials (RCTs), including cross―over RCTs with a minimum washout period of two weeks. Quasi―RCTs if baseline characteristics of intervention groups are similar (Higgins 2011b)

# **Participants**

Individuals of all ages, with a confirmed diagnosis of CF by genotype or sweat chloride testing, with and without PI.

#### Interventions

Regimens pre―specifying different administration timings (e.g. before, during or after a meal) in any dosage (dose/kg body weight or dose/g ingested fat or any other strategy) or formulation of PERT in people, of any age, with CF.

#### **Outcome measures**

Primary outcomes: Fat malabsorption (absolute CFA based on 72―hour stool collection); Nutritional status (change from baseline); weight in kg, % of predicted weight or z score; height in cm, % of predicted height or z score; BMI, % of predicted BMI or z score; Adverse events

## Main results

No studies met the eligibility criteria and therefore we did not include any in this review. The excluded studies were either cross―over in design (but lacking a sufficient washout period between treatments) or did not assess the timing of PERT. One study which was terminated early is awaiting assessment pending further information.

## **Authors' conclusions**

We were unable to determine whether one dosing schedule for PERT is better than another since we identified no eligible RCTs. While the introduction of PERT to people with CF can improve their nutritional status, there are a limited number of studies which address this review question, and none met our eligibility criteria. Since malnutrition and adverse gastrointestinal symptoms remain a common feature in CF, the assessment of the relative performance of dosing schedules may provide evidence to improve outcomes in people with CF who are pancreatic insufficient. Further research is needed to fully evaluate the role of dosing schedules for PERT in fat absorption. Research should also establish reliable outcome measures and minimal clinically important differences. While RCTs with a cross―over design may have advantages over a parallel group design, an adequate washout period between intervention periods is essential.

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# See also

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# Keywords

Gastrointestinal Diseases; pharmacological\_intervention; Pancreas insufficiency; Pancreatic Diseases; Pancreatic Enzyme Replacement Therapy; Malabsorption; Nutrition Disorders; Gastrointestinal Agents;