Enzyme substitution in exocrine pancreatic insufficiency; Self administration against a fixed dose regimen.

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To assess the difference in efficacy of pancreatic enzymes in a self-dosage regimen after extensive patient-education in comparison to the standard treatment for patients with EPI.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON35552

Source
ToetsingOnline

Brief title
SAPES

Condition

- Exocrine pancreas conditions
- Lipid metabolism disorders

Synonym
enzyme suppletion, Exocrine pancreatic insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Axcan Pharma

Intervention

Keyword: chronic pancreatitis, comparative clinical trial, enzyme substitution, exocrine pancreatic insufficiency

Outcome measures

Primary outcome

The primary endpoint is the faecal fat absorption.

Secondary outcome

Secondary objectives are:

1. Change in enzyme dose after intervention

2. Improvement of complaints (e.g. steatorrhoea, abdominal cramps, abdominal

pain).

5. Change in dietary habits

6. Patient satisfaction

7. Quality of life

3. Evaluation of the nutritional status

Study description

Background summary

Treatment of EPI consists of pancreatic enzyme replacement according to the fat intake. Prescribing a sufficient dose of pancreatic enzymes is mandatory for the treatment to be effective. In addition, consultation of a specialized dietician is pivotal to educate patients about the proper use of pancreatic enzymes. However, based on a recent prospective survey in the Netherlands amongst CP patients, it seems that enzymes are underused and a dietician is seldom consulted. Half of the patients use <= 6 capsules of 25.000 FIP-E units of lipase a day and a quarter use <= 3 capsules of 25.000 FIP-E units of lipase a day. With the median enzyme dose, 69% of patients reported to have

steatorrhoea related complaints and 42% of patients had difficulties maintaining weight. In order to improve efficacy, physicians should increase the dosage of pancreatic enzymes. More patients should be referred to a dietician. However, the quality of dietary advice should be improved by better training of (specialized) dieticians.

Study objective

To assess the difference in efficacy of pancreatic enzymes in a self-dosage regimen after extensive patient-education in comparison to the standard treatment for patients with EPI.

Study design

This is a prospective, open, comparative study with a linear design with two sequential phases (observeratory, then patient-monitored).

Intervention

Drawing blood
Feces fat balance
Start treament with pancreatic enzymes together with extensive patient education

Study burden and risks

Because the maximum amount of 16 capsules of pancreatic enzymes a day according to the standard guidelines and the Farmacotherapeutisch Kompas will not be exceeded in this trial, no serious events are foreseen in the medication prescribed during this trial. The anticipated benefit of the study is that patients after completion are properly dosed and well treated for their exocrine insufficiency.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients considered for this trial:
- are older than 18 years.
- suffer from EPI caused by CP.
- Fecal Elastase < 0.200 mg/g
- are using <= 6 capsules of 25.000 FIP-E units of lipase per day.
- fecal fat-absorption < 85% without using enzymes.

Exclusion criteria

The following are considered as exclusion criteria:
- Subjects who are unwilling or unable to understand and participate in the study and sign the informed consent.
- Any known gastro-intestinal disease or major gastrointestinal or pancreatic surgery that could potentially affect the intestinal absorption or metabolism of fat
- Gastroparesis of any aetiology
- Hypersensitivity to pork protein
- Acute pancreatitis
- Limited life-expectancy of <= 6 months
- Malignancy of the pancreas
- Pregnancy/lactation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Panzytrat
Generic name:	pancreatine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	15-09-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	19-09-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-020303-69-NL
CCMO	NL29316.078.10