Optimalisation of exocrine pancreatic insufficiency and pancreatic enzyme replacement therapy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Observational non invasive

Summary

ID

NL-OMON52709

Source
ToetsingOnline

Brief title
OPPERT-study

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Exocrine pancreatic insufficiency, impaired exocrine pancreatic function

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Cancer Center Amsterdam

Intervention

Keyword: Exocrine pancreatic insufficiency, Gastrointestinal surgery, Pancreatic cancer, Periampullary cancer

Outcome measures

Primary outcome

Primary outcome measure is diagnostic accuracy of easy diagnostic test(s) and

the presence of steatorrhea-related symptoms to diagnose EPI, compared to the

72-hour faecal fat quantification.

Secondary outcome

- presence of micronutrient deficiencies

- incidence of EPI in this patient group

- evaluate whether the occurrence of EPI can be predicted based of specific

signs and symptoms

- evaluate the effect of changes in therapy based on the results of the

diagnostic tests included in this study

- evaluate the effect of EPI on overall quality of life in postoperative

patients

Study description

Background summary

In patients with cancer of the periampullary region, weight loss is a serious problem, affecting 80% already at diagnosis. For this, both primary and secondary tumour effects are responsible. Exocrine pancreatic insufficiency (EPI) is a secondary tumour effect, in which the pancreas is unable to deliver sufficient pancreatic enzymes into the small intestinal lumen to digest food. It may occur due to gland atrophy, obstruction of the pancreatic duct, anatomical changes or removal of functional pancreatic tissue after surgery. A

shortage of pancreatic enzymes causes maldigestion, primarily of fat, leading to steatorrhea-related symptoms, weight loss, malnutrition, and an impaired quality of life. This not only affects patients with cancer of the periampullary region, it can also affect patients who underwent gastrointestinal surgery for cancer, including a pancreatoduodenectomy (PD), gastrectomy, or esophagectomy. To prevent these symptoms patients should be treated with an adequate dosage of pancreatic enzymes. The gold standard to diagnose EPI is the 72-hour faecal fat quantification. This is a time-consuming and burdensome test, as patients need to follow a strict diet of 80-100 grams of fat during 5 days and collect all stool during the last 72 hours. The Faecal Elastase-1 Test (FET), is currently mostly used in clinical practice, as only a small stool sample is needed without any dietary restrictions. Previous studies, including a pilot study from the Amsterdam University Medical Center, suggest that the FET is possibly less accurate to detect EPI in patients after gastrointestinal surgery. Aim of this study is to investigate the value of several diagnostic tests, including a shortened version of the current gold standard test, to detect EPI in these patients.

Study objective

Primary aim of this study is to validate easy and reliable tests to detect EPI in patients after gastrointestinal surgery. The 72-hour faecal fat quantification (gold standard), will be compared with a shortened version of 24-hours, the FET and 13C-mixed triglyceride (13C-MTG) breath test. These parameters will also be compared with the presence of steatorrhea-related symptoms. Secondary endpoints are presence of micronutrient deficiencies, incidence of EPI in this patient group and to evaluate whether the occurrence of EPI can be predicted based of specific signs and symptoms.

Study design

Prospective observational cohort study

Study burden and risks

In current practice, there is no unequivocal protocol to supplementation of pancreatic enzymes after gastrointestinal surgery. As a result patients may be undertreated or over treated, often without objective confirmation of exocrine insufficiency trough a valid diagnostic test. The benefit of participating in this study is that patients will undergo diagnostic tests to objectively determine the presence of EPI. As a result, all patients with confirmed EPI will be treated with pancreatic enzymes. Burden of this study is expected to be low, as patients will undergo several diagnostic tests, most of them part of standard clinical care. Therefore no serious events are foreseen for patients joining this study.

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

1) Age * 18 years;
2) Written informed consent;
3) Understanding of the Dutch language;
4) Willing and capable of following the instructions for this study;
5) Patients need to be able to achieve a minimal daily dietary fat intake of *
60 grams.

Exclusion criteria

1) Any known gastrointestinal disease or major gastrointestinal surgery (apart
from a PD, esophagectomy, gastrectomy) that could potentially affect the

intestinal absorption or metabolism of fat (e.g. short bowel, irritable bowel disease, cystic fibrosis, chronic pancreatitis among others).
2) Gastroparesis of any aetiology (not applicable for group III and IV) .
3) Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the treating physician.
4) Patients who are unable to cease anti-diarrheal medication or laxatives, based on the physician*s experience.
5) Patients who are suspected not to be reliable in participating in this study, based on the physician*s experience.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	23-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL68432.029.19