Optimalisation of exocrine pancreatic insufficiency and pancreatic enzyme replacement therapy in patients with periampullary cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25332

Source
Nationaal Trial Register

Brief title
OPPERT

Health condition

Periampullary cancer / Pancreatoduodenectomy

Sponsors and support

Primary sponsor: Cancer Center Amsterdam
Source(s) of monetary or material Support: Cancer Center Amsterdam

Intervention

Outcome measures

Primary outcome

Primary endpoint of this study is diagnostic accuracy of various diagnostic tests such as the

FET, the 13C-MTG breath test and the 24-hour faecal fat quantification, Sudan stain test compared to the 72-hour faecal fat quantification to detect EPI in patients with a newly diagnosed periampullary cancer and after a PD.

Secondary outcome

1) Incidence of EPI at time of diagnosis of periampullary cancer and after a PD
2) Course of exocrine pancreatic function after a PD
3) Presence of micronutrient deficiencies
4) To evaluate whether the occurrence of EPI can be predicted based on the development of specific signs or symptoms

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. 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 with pancreatic cancer and after a pancreatoduodenectomy (PD). 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

Based on a pilot study from the Amsterdam University Medical Center, we hypothesize that the FET is possibly less accurate to detect EPI in patients with pancreatic cancer and after a pancreatoduodenectomy (PD).

Study design

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

1) Age > 18 years
2) Written informed consent
3) Understanding of the Dutch language
4) Willing and capable of following 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) that could potentially affect the intestinal absorption or metabolism of fat
2) Gastroparesis of any aetiology
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
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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2019
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-09-2019
Application type:	First submission

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
NTR-new	NL8038
Other	METC VUmc : METC 2019.210

Study results