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

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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).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25332

Bron
Nationaal Trial Register

Verkorte titel
OPPERT

Aandoening

Periampullary cancer / Pancreatoduodenectomy

Ondersteuning

Primaire sponsor: Cancer Center Amsterdam
Overige ondersteuning: Cancer Center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

Not applicable

Contactpersonen

Publiek

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Lotte Blonk

0204444444

Wetenschappelijk

Amsterdam UMC, location VUmc
Lotte Blonk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-09-2019
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8038
Ander register	METC VUmc : METC 2019.210

Resultaten