Added value of digital PET in (re)staging patients with pancreatic cancer

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Digital PET improves response evaluation compared to conventional methods

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22880

Bron
NTR

Verkorte titel
PANDIGIPET

Aandoening

pancreatic cancer, response assesment, digital PET

Ondersteuning

Primaire sponsor: Isala hospital, Zwolle, the Netherlands
Overige ondersteuning: Isala Innovatie en Wetenschapsfonds, Philips Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic outcome digital PET/CT

Toelichting onderzoek

Achtergrond van het onderzoek

For pancreatic cancer, surgery is the only treatment method that can potentially cure the patient. Currently only 20% of the patients are eligible for a surgical resection with curative intention. A recent development in pancreatic cancer treatment is the use of neo-adjuvant chemotherapy before surgery and this has already shown good clinical results. In these patients, contrast-enhanced Computed Tomography scans (ceCT) of the abdomen are acquired for (re)staging. However, response evaluation with CT scans is unreliable because it is not possible to distinguish between post-treatment fibrosis and malignancies. Recently, a novel digital PET/CT system was introduced in Isala, which provides PET images that are significantly more detailed and accurate as compared to the analog PET systems. Furthermore, the tumour marker Serum Ca 19.9 is widely used for pancreatic adenocarcinoma and has shown its value in the assessment of response to neo-adjuvant therapy. The aim of this study is to evaluate the diagnostic value of digital PET/CT as a staging and restaging imaging modality, as compared with ceCT and Ca 19.9, in patients with resectable or borderline resectable pancreatic cancer, who are treated with neo-adjuvant therapy before surgery.

Doel van het onderzoek

Digital PET improves response evaluation compared to conventional methods

Onderzoeksopzet

First FDG-PET/CT scan and second FDG-PET/CT scan

Onderzoeksproduct en/of interventie

Participants will undergo two FDG-PET/CT scans on a digital PET/CT system, before the start of the treatment and after neo-adjuvant chemotherapy treatment

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Histological or cytological confirmed malignant peri-ampullary tumour, resectable or borderline resectable, without evidence of distant metastases

-Inclusion in the PREOPANC-2 study

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 years

- Incapacitated adults

- Prisoners

- Pregnancy

- Unable to undergo a FDG-PET/CT scan

- Metastatic or locally advanced (i.e. unresectable) pancreatic cancer

- Ampullary or distal bile duct cancer.

- Prior radiotherapy, chemotherapy, or resection for pancreatic cancer

- Previous malignancy (excluding non-melanoma skin cancer), unless no evidence of disease and diagnosed more than 2 years before diagnosis of pancreatic cancer

- 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 investigator.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
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:	01-07-2018
Aantal proefpersonen:	40
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:	23-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46552
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7243
NTR-old	NTR7442
CCMO	NL64320.075.17
OMON	NL-OMON46552

Resultaten