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

Published: 19-03-2018
Last updated: 15-05-2024

to determine 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 (borderline) resectable pancreatic cancer

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON46552

Source
ToetsingOnline

Brief title
(Re)stadiering of digital PET in pancreatic cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
cancer of the pancreas, pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: I&W fonds Isala en Philips Healthcare,Philips

Intervention

Keyword: digital PET/CT, pancreas cancer, staging

Outcome measures

Primary outcome

Diagnostic value (sensitivity, specificity, accuracy) of digital PET/CT for

staging and response assessment

Secondary outcome

Correlation of staging data and restaging data with tumor marker CA 19.9 serum

levels.

Study description

Background summary

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 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 tumor 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.

Study objective

to determine 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

(borderline) resectable pancreatic cancer

Study design

Single center diagnostic accuracy study using intra-individual comparisons of FDG-PET/CT scans and ceCT scans

Study burden and risks

• Additional wait time and scan time: For each patient included in this study, two FDG-PET/CT scans will be performed in a four months* time period. Before injection of FDG, patients have to be sober for at least 6 hours. After intravenous injection of FDG, the patient has to lie down for approximately 50 minutes in a separate room, before the PET/CT acquisition will start. Furthermore, the PET/CT acquisition itself will take on average 20 to 30 minutes, including performing the attenuation CT, in which the patients have to lie still on a scanner bed.
• Additional radiation dose: The two study-related FDG-PET/CT scans will give an additional radiation dose of on average 8 milliSievert (mSv), per scan. In comparison: for the diagnostic ceCT that is routinely performed multiple times in pancreatic cancer patients, the average dose is 14 mSv.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Histological or cytological confirmed malignant peri-ampullary tumour, resectable or borderline resectable, without evidence of distant metastases.
• Inclusion in the Preopanc-2 study and randomized for neo-adjuvant chemotherapy
• Written informed consent
There is an additional inclusion criterion for the acquisition of the second FDG-PET/CT scan: only patients that are treated with at least 4 cycles, and a maximum of 8 cycles of neo-adjuvant chemotherapy will be referred for this FDG-PET/CT scan.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• 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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22880
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64320.075.17
OMON	NL-OMON22880