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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22880

**Source**
NTR

**Brief title**
PANDIGIPET

**Health condition**

pancreatic cancer, response assesment, digital PET

### Sponsors and support

**Primary sponsor:** Isala hospital, Zwolle, the Netherlands
**Source(s) of monetary or material Support:** Isala Innovatie en Wetenschapsfonds, Philips Healthcare

### Intervention

### Outcome measures

**Primary outcome**

Diagnostic outcome digital PET/CT

**Secondary outcome**

Correlation FDG-uptake with Ca 19.9

# 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/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.

### Study objective

Digital PET improves response evaluation compared to conventional methods

### Study design

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

### Intervention

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

- 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

## Exclusion criteria

- 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: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-07-2018 |
| Enrollment: | 40 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 23-08-2018 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 46552

Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results