# Optimization of 4D-CT in the Diagnostic Workup of Tumors of the Pancreas

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON37591

**Source**
ToetsingOnline

**Brief title**
CT perfusion in pancreatic tumors

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
pancreas tumor

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** CT perfusion pancreas tumor

## Outcome measures

### Primary outcome

1. Radiation dose for the combined diagnostic and perfusion scan

2. Detection of the pancreas tumor with a perfusion scan compared to a regular

diagnostic scan

3. Detection of liver metastases with a perfusion scan compared to a regular

diagnostic scan

### Secondary outcome

none

# Study description

### Background summary

Patients with painless jaundice require an ultrasound, CT and/or MRI of the abdomen to diagnose the cause of obstruction. Possible causes are a stone or tumor in the common bile duct, an inflammation or a cystic or solid tumor in the head of the pancreas. In case of a tumor the exact location, its extent to surrounding structures and the presence of locoregional and distant metastases have to be determined.

Patients with a tumor in the pancreas are usually diagnosed with a CT of the thorax and abdomen. The CT scan acquisition is composed of a non-contrast enhanced series, followed by a contrast-enhanced series in the arterial phase and in the porto-venous phase (Figure 1).

Recently a new CT scanner (Aquilion ONE, 320 row, Toshiba Medical Systems, Ohtawara, Japan) has been installed at the Department of Radiology enabling dynamic volumetric scan covering up to 16 cm in length, at minimum 0.35 seconds rotation time; specifications that have been unmatched before. This new technique permits dynamic volumetric imaging of the pancreas and liver, making it possible to perform time-resolved functional studies (Figure 1). This may

improve early detection of liver metastases and improve detection and characterization of the primary pancreatic tumor.

Until now, a diagnostic scan and perfusion CT scan are performed in two separate steps, each requiring a contrast injection. With the new dynamic volumetric scan technique both steps can be combined, resulting in one CT scan with only one contrast injection and with both diagnostic and perfusion characteristics available. However, as it is a new technique, it is necessary to optimize the CT scan parameters, regarding respiration technique, the number of necessary time points in the arterial and porto-venous phase and radiation dose per time point.

When compared to a normal diagnostic scan, the data obtained with a perfusion scan are likely to improve the detection and characterization of the pancreatic tumor. This will lead to a better staging of the tumor resulting in a better selection of therapy, either curative resection (Whipple operation) or palliative chemo-radiation therapy. With better staging non-curative resections can be avoided, reducing morbidity and increasing quality of life.

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Fig. 1. Time density curve. Contrast enhancement in Hounsfield units (HU) as a function of time (t) in seconds (s). A CT scan-protocol in which a diagnostic and perfusion scan are performed during one intravenous contrast injection. Phase I, II and III are the non-contrast enhanced (t=0s), and arterial (t=35s) and porto-venous (t=65s) contrast-enhanced diagnostic scans respectively. The curve (red) represents the data acquired at regular time intervals during the perfusion scan.

**Study objective**

With this pilot study our aim is to lower the radiation dose. Therefore we will scan 5 patients at 100kV and 5 patients at 80kV and determine the resultant decrease in radiation dose, aiming at a dose comparable with a normal diagnostic CT scan with 3 phases. This can be achieved by optimizing the number of time points, the dose per time point and combining perfusion data to create diagnostic data. In the latter case, less diagnostic scans are necessary. The use of adaptive iterative dose reduction (AIDR 3D) will reduce the radiation dose even more. This technique just recently became available (in October 2011).

The acquired data will result in an optimized CT scan protocol regarding the minimally required data to perform a time-based functional study with the unique capability to combine it with a diagnostic scan and with it a as low as possible radiation dose. The final aim is to improve staging and characterization of pancreatic tumors resulting in less non-curative resections with associated postoperative morbidity and improve quality of life.

**Study design**

Number of included patients: n=10.

Inclusion criteria:
- Patients with a suspected tumor in the head of the pancreas.
- Older than 18 years

Exclusion criteria:
- Non post menopausal women
- Transpapillary endoprosthesis in situ
- Previous surgery of the pancreas
- Previous chemoradiation therapy of the pancreas
- Patients with active hepatitis or other hepatic diseases that may cause jaundice
- Informed consent not obtained

Respiration protocol:
A band will be applied around the upper abdomen to restrict movements of the abdominal wall during normal respiration. Before the start of the scan the patient is asked to hyperventilate for a minute, in order to obtain a quiet and even respiration during scanning.

Specifications of contrast administration:
- Contrast agent: Xenetix 300mgI/ml
- Amount contrast agent: 0,5 - 0,6g I/kg bodyweight
- Injection rate: 3-10ml/s
- No delay between start of scan and start of injection
With the new CT scan the amount of contrast agent, used for combined perfusion and diagnostic imaging, is the same as that of a standard diagnostic scan. The renal function of patients will be monitored according to the current standards for the administration of intravenous contrast agents.

Specifications of radiation dose (estimated):
- Normally: a diagnostic CT scan with 3 phases (kV = 120; mA variable): 12-26 mSv
o at T = 0s: non-contrast enhanced helical CT upper abdomen
o at T = 35s: contrast-enhanced helical CT upper abdomen
o at T = 65s: contrast-enhanced helical CT thorax and abdomen
- Study: a diagnostic CT scan with 3 phases and perfusion CT scan (kV = 80/100; mA variable): 36-50 mSv
o at T = 0s: non-contrast enhanced helical CT upper abdomen
o T = 0 - 300s (perfusion): contrast-enhanced upper abdomen
o at T = 35s: contrast-enhanced helical CT upper abdomen
o at T = 65s: contrast-enhanced helical CT thorax and abdomen
The extra radiation dose with the scan technique in this pilot is high, and

doubles the effective dose for the patient (European Guidelines on Quality Criteria for Computed Tomography, EUR 16262 EN, Table 2, p70). The perfusion scan of the upper abdomen will result in an additional radiation dose of 24 mSv. The additional risk for this specific oncologic patient group is almost negligible. Patients diagnosed with pancreatic cancer have a 1 year survival of 20% and a 5 year survival of 5%. For local disease the 5 year survival is approximately 20%, while the median survival for locally advanced and for metastatic disease is about 10 and 6 months respectively. Five year survival after curative resection of a adenocarcinoma in the head of the pancreas is 5-10%. Radiation-induced cancer has a latency period that substantially exceeded 5 years.

With the already implemented new software (AIDR-3D) the total estimated radiation dose is reduced to 20-36mSv (see paragraph on risks associated with participation).

Data analysis:
- The results of the diagnostic CT scans are part of the regular workup for patients with a pancreatic tumor and will be discussed in the weekly pancreatic tumor working group (PACON), resulting in a treatment plan.
-The perfusion data will be analyzed separately.
oSoftware for registration to compensate for possible movement during scanning and perfusion analysis, as available on the Toshiba workstation, will be compared with software analysis tools developed in-house by DIAG using MeVisLab software development environment.
oThe number of time points will be optimized regarding radiation dose and perfusion parameters.
oTo combine perfusion data to create a diagnostic scan. Omission of a diagnostic scan will result in a reduction of the radiation dose.
oWith the use of iterative reconstruction, a new technique to reconstruct images, image quality (signal to noise ratio (SNR)), can be improved. This data are used to calculate dose reduction protocols for future patients.

**Study burden and risks**

The risk associated with participation in this study is the extra radiation dose involved in the additional perfusion scan.

With the recent implementation of adaptive iterative dose reduction (AIDR-3D) software in October 2011, the radiation dose can be diminished. We tested the new software on a phantom (CT Torst Phantom CTU-41, Kyoto Kagaku Co., Ltd) with the CT scan protocol as described above. The resulting estimated dose reduction depending on the size of the patient (20
Old software (QDS+):
- diagnostic scan : 12-26mSv (20 - perfusion scan (100kV) : 24mSv
TOTAL: 36-50mSv

New software (AIDR-3D):
- diagnostic scan : 4-20mSv (20 - perfusion scan (100kV): 16mSv
TOTAL: 20-36 mSv

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Patients with a suspected tumor in the head of the pancreas.
Older than 18 years.

## Exclusion criteria

Previous surgery of the pancreas
Previous chemoradiation therapy of the pancreas
Transpapillary endoprosthesis in situ
Patients with active hepatitis or other hepatic diseases that may cause jaundice
Informed consent not obtained

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-12-2011 |
| Enrollment: | 10 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 09-01-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 |
| --- | --- |
| CCMO | NL38686.091.11 |