18F-Prostate Specific Membrane Antigen PET-CT as a potential novel imaging modality for pancreatic cancer: A pilot study (PANSCAN-2)

Published: 26-05-2020
Last updated: 17-01-2025

To investigate the feasibility of using 18F-PSMA PET-CT as a tumor-specific molecular imaging in PC, thus allowing for improved detection, therapy selection, and therapy response assessment.

Ethical review	Approved WMO
Status	Completed
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON52415

Source
ToetsingOnline

Brief title
PANSCAN-2

Condition

- Exocrine pancreas conditions

Synonym
pancreas carcinoma, pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: CCA grant (Cancer Center Amsterdam)

Intervention

Keyword: 18F-PSMA, pancreatic cancer

Outcome measures

Primary outcome

Primary endpoint: feasibility of 18F-PSMA PET-CT for detection of pancreatic adenocarcinoma in patients with clinically suspected or histological -proven resectable PC, prior to surgery (*qualitative* visual evaluation).

Secondary outcome

Secondary endpoints: (1) the correlation between localisation 18F-PSMA uptake on PET-CT and PSMA expression in tissue using immunohistochemistry, and (2) the identification of the lower limit of PSMA expression on tissue samples still resulting in detectable tumours (18F-PSMA *positivity*) on the PET scan (*quantitative* evaluation). This in order to select eligible patients for PSMA-based therapy in the future.

Study description

Background summary

Theoretical and empirical background of the project proposal:
- In the Netherlands, PC has an incidence of 3.000 new cases per year and is associated with a dismal prognosis.2 This is mainly due to difficulty in early detection of the disease. Staging, and hence rational use of treatment, is highly dependent on information yielded from conventional imaging modalities (e.g., CT, MRI, EUS). However, almost 50% of surgery is without patient benefit (e.g., due to benign diagnoses, undetected metastases, or recurrence <6 months), indicating that these imaging modalities are lacking diagnostic precision and response evaluation accuracy. In surgery for PC, 10% show metastases at laparoscopy and approximately half of the patients undergoing a

resection will have microscopically positive resection margins (R1), of whom 25% will develop disease recurrence within six months after surgery. Furthermore, the imaging in patients with locally advanced PC who started chemotherapy is unreliable.3
Also, 18F-FDG PET-CT has no place in standard health care, mainly due to the large number of false positive findings, resulting in futile resections of the pancreas. 18F-FDG PET-CT is therefore only reserved on indication for the individual patient.3
- Molecular imaging with 18F-PSMA PET may be a promising diagnostic alternative (figure 1). PSMA is a type II transmembrane glycoprotein highly expressed on the surface of prostatic cancer epithelial cells. The expression of PSMA in tumour-associated (neo)vasculature of prostate cancer, breast cancer and primary gliomas has been reported, and is proven to be also high in PC.5,6
- 18F-PSMA PET has been recently technically validated and successfully implemented in clinical practice for prostate cancer at Amsterdam UMC, VUmc.7 Radiolabelled PSMA PET-CT has proven highly successful for primary staging and restaging of prostate cancer patients and is currently being implemented worldwide.8
- Recently, it has been shown that PSMA is also expressed on the endothelium of tumour-associated neovasculature in PC tissue, in 63-84% of the investigated samples. 5,6 Immunohistochemical experiments from our group showed an acceptable high expression of PSMA in 4 out 5 patients with PC de novo, as well as in 32 out 33 PC patients after neoadjuvant treatment (mean tumor H-score of 99 (maximum 300)), comparable with the reported results in the literature. These experiments also showed no expression on adjacent normal and pancreatitis tissue (H-score 0), thus yielding high contrast (figures 2 and 3).

Study objective

To investigate the feasibility of using 18F-PSMA PET-CT as a tumor-specific molecular imaging in PC, thus allowing for improved detection, therapy selection, and therapy response assessment.

Study design

The PANSCAN-2 study will be a non-blinded, two locations (Amsterdam UMC) pilot study.

Intervention

The study intervention comprises one 18F-PSMA PET-CT scan prior to treatment initiation.

Study burden and risks

The burden of study participation is low. Patients will undergo one extra

18F-PSMA PET/low-dose CT (for attenuation and anatomical correlation), additional to all standard imaging modalities prior to pancreatic surgery (e.g. diagnostic CT thorax/ abdomen). The only additional risk of this scan for patients is the intravenous access cannula followed by administration of 18F-PSMA; which could give a local hematoma, run subcutaneously or give an allergic reaction.

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 aged 18 years or older
- Diagnosis of suspected pancreatic ductal adenocarcinoma and eligible for surgery
- Before patient registration, written informed consent must be given according

to ICH/GCP, and national/local regulations.

Exclusion criteria

- Patients with metastatic PC will be excluded, as current guidelines exclude them from surgery because of no survival benefit.
- Women who are pregnant and/or or lactating.
- Medical or psychiatric conditions that compromise the patient*s ability to give informed consent. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.
- Prior radiotherapy to the abdomen and/or thorax.
- Unacceptable known (clinically significant) cardiovascular or pulmonary disease, renal or liver dysfunction, which could hamper participation in this study or jeopardize the patients* health.
- Known hypersensitivity to drugs comparative to 18F-PSMA, or any of their excipients or to any component of 18F-PSMA.
- Inability to undergo PET/CT scanning (e.g. claustrophobia, weight limits or inability to tolerate lying for the duration of a PET/CT scan (~30 min).
- Inability to undergo routine MRI or CT scans as part of the diagnostic work up.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	23-02-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]DCFPyL
Generic name:	[18F]DCFPyL

Ethics review

Approved WMO Date:	26-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2020-002185-14-NL
CCMO	NL73356.029.20

Study results

Date completed: 22-06-2023

Results posted: 27-02-2024

First publication
27-02-2024