Prostate Cancer Imaging with [18Flourine]Prostate Specific Membrane Antigen (PSMA) PET: a study on pharmacokinetics and test repeatability

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The present study aims to:A) acquire a pharmacokinetic model of [18F]PSMA ([18F]-DCFPyl), by which simplified methods to quantify [18F]PSMA PET signal will be validated ; andB) assess the repeatability of those simplified quantitative method.

Ethical review	Approved WMO
Status	Completed
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45317

Source
ToetsingOnline

Brief title
Pharmacokinetics and repeatability of [18F]PSMA

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer; prostate malignancy; neoplasm of the prostate

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting VUmc CCA

Intervention

Keyword: cancer, PET, pharmacokinetics, prostate, PSMA, repeatability

Outcome measures

Primary outcome

Part A

A pharmacokinetic model for [18F]PSMA and an appropriate simplified

quantitative method.

Part B

Test-retest variability of the simplified method of choice (part A) implemented

in dynamic thoracic and WB [18F]PSMA PET/CT.

Secondary outcome

not applicable

Study description

Background summary

[18F]Prostate Specific Membrane Antigen ([18F]PSMA) is a relatively new oncological tracer used to perform Positron Emission Tomography * Computed Tomography ([18F]PSMA PET-CT) scans. PSMA is a type II membrane glycoprotein significantly overexpressed in prostate cancer cells. Presently, the main application of this tracer is restaging in patients with prostate cancer (PCa). In order monitor treatment response too, accurate quantification of [18F]PSMA signal is important beyond visual image interpretation. For quantification of PET tracers, full pharmacokinetic analysis is the golden standard. However, its complexity makes it unsuitable for application in daily clinical practice; moreover, it is not compatible with the whole body acquisitions typically required in patients with metastasised disease. Therefore, simplified measurements applicable with whole body scanning must be validated versus the

reference technique. Finally, to allow proper interpretation of signal changes over time, the intrinsic repeatability of the simplified method of choice should be defined. A better knowledge of the pharmacokinetics and repeatability data could lead to an optimization of [18F]PSMA PET-CT diagnostic potential. This might improve personalized therapy strategies for prostate cancer patients.

Study objective

The present study aims to:
A) acquire a pharmacokinetic model of [18F]PSMA ([18F]-DCFPyl), by which simplified methods to quantify [18F]PSMA PET signal will be validated ; and
B) assess the repeatability of those simplified quantitative method.

Study design

A mono-center, prospective observational study in 20 patients with metastasized prostate cancer. The study consists of two parts: part A, the [18F]PSMA pharmacokinetics, and part B, the repeatability of [18F]PSMA estimates.
A. In the first part, both PSMA expression ([18F]PSMA) and perfusion (H215O) will be measured quantitatively in 8 patients. Accuracy of blood and plasma activity concentration, plasma metabolite measurements derived from arterial and venous samples as well the reliability of using Image Derived Input Functions (IDIF) for quantification of [18F]PSMA kinetics will be tested in eight patients. Dynamic scanning will be performed on one occasion, using 2 tracers: H215O and [18F]PSMA.
B. In the second step of the protocol, depending on the obtained validation in part A, the repeatability of the method will be tested in 12 other patients, on two separate occasions (at most one week apart) using a whole body (WB) [18F]PSMA PET-CT scan. For accurate reproducible measuring, a dynamic PET-CT of the thorax region, will proceed the performing of the WB scan.

Study burden and risks

The total amount of radiation burden will be lower than 8.5 mSv during the entire part A study. The total amount of radiation burden for part B will not exceed 18 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

Part;
- Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastases;
- Written informed consent;
- At least 2 metastases in the thorax per patient detected by conventional imaging (e.g., bone scan, either CT or MRI of the chest, abdomen and pelvis); conventional imaging should be recently performed (no longer than 3 months previous to the PET-CT scan);
- At least one tumour (metastasis) with diameter * 1.5 cm (to minimize partial volume effects);
- Patients able to remain supine for 60 minutes in the PET-CT scanner;;Part B;
- Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastases;
- Written informed consent;
- At least one tumour (metastasis) with diameter >1.5 cm detected by recently performed conventional imaging (maximal 3 months prior to the PET-CT scan);
- Patients able to remain supine for 80 minutes in the PET-CT scanner;

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Claustrophobia (part A and B);
- Multiple malignancies (part A and B);
- Participation part A (Part B)

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-01-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]DCFPyl ([18F]PSMA)
Generic name:	2-(3-(1-carboxy-5-[(6-[18F]fluoro-pyridine-3-carbonyl)-amino]-pentyl)-ureido)-pentanedioic acid
Product type:	Medicine
Brand name:	H2-15O
Generic name:	H2-15O

Ethics review

Approved WMO Date:	28-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2017
Application type:	First submission
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	EUCTR2017-000344-18-NL
CCMO	NL61224.029.17

Study results

Date completed:	26-05-2019
Results posted:	10-03-2020

First publication
10-03-2020