The PSMA-PET scan: a study on tracer properties and test repeatability

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24408

Source
NTR

Brief title
PImPAnPET

Health condition

(metastasized) prostate cancer

(gemetastaseerde) prostaatkanker

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam
Source(s) of monetary or material Support: CCA VUmc Foundation

Intervention

Outcome measures

Primary outcome

Part A: A pharmacokinetic model for [18F]PSMA ([18F]DCFPyl) and a validated simplified quantitative method for [18F]PSMA PET-CT.

Part B: Test-retest variability of the derived simplified method (Part A).

Secondary outcome

none

Study description

Background summary

SUMMARY

Rationale: [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 of patients with prostate cancer (PCa). To also be able to monitor treatment response, 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 (WB) acquisitions typically required in patients with metastasized disease. Therefore, simplified measurements applicable with whole body scanning must be validated versus the reference technique. Once established, the intrinsic repeatability of the simplified method of choice should be defined, to allow proper interpretation of signal changes over time. A better understanding of the pharmacokinetics and repeatability of [18F]PSMA could lead to an optimization of the [18F]PSMA PET-CT diagnostic potential. This might aid diagnostic accuracy, needed for personalized therapy strategies in prostate cancer patients.

Objective: The aims of the present study are:

A) to acquire a pharmacokinetic model of [18F]PSMA ([18F]DCFPyl) by which simplified methods to quantify [18F]PSMA PET signal will be validated; and

B) to assess the repeatability of these simplified quantitative methods.

Study design: A mono-center, prospective 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 PET measurements.

A) In the first part, both PSMA expression ([18F]PSMA) and perfusion (H2-15O) will be measured quantitatively in 8 patients using a dynamic scanning protocol. 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.

B) In the second step of the protocol, the repeatability of the simplified quantitative method found in Part A will be tested in 12 other patients. For all patients, a scanning procedure including a WB [18F]PSMA PET-CT will be performed on two separate occasions (at most one week apart).

Study population: Patients with histologically proven metastasized prostate carcinoma. Intervention: Part A procedure consists of a 10 min PET study after intravenous (iv) administration of H215O, followed by a second 60 min PET study directly after [18F]PSMA administration. The procedure then includes a 30 minutes break, followed by a last dynamic scan 90-120 minutes post injection. Accuracy of blood and plasma activity concentration, plasma metabolite measurements derived from arterial and venous samples as well as the reliability of using Image Derived Input Functions (IDIF) for quantification of [18F]PSMA kinetics will be tested.

Part B Following results of Part A, a scanning protocol consisting of a WB PET-CT after administration of [18F]PSMA will be performed. This procedure will be repeated within a maximum of 7 days.

Main study parameters/endpoints: Part A: A pharmacokinetic model for [18F]PSMA ([18F]DCFPyl) and a validated simplified quantitative method for [18F]PSMA PET-CT. Part B: Test-retest variability of the derived simplified method (Part A).

Study objective

Part A

The main objective of this part of the study is to develop a pharmacokinetic model for [18F]PSMA. Furthermore, use of simplified quantitative methods and procedures will be performed and validated against full quantitative kinetic measures, in order to select reliable simplified methods for clinical use. Perfusion measurements are included and required to assess to what extend full quantitative kinetic model and simplified methods are affected by perfusion and tracer delivery. Lastly, acquisition and data analysis methods will be optimized for routine clinical studies.

Part B

The objective of this part of the study is to evaluate the test-retest repeatability of different quantitative measurements (e.g. SUVs, metabolic and anatomic volumes) on [18F]PSMA PET - as derived from Part A.

Study design

not applicable

Intervention

Part A procedure consists of a 10 min PET study after intravenous (iv) administration of H215O, followed by a second 60 min PET study directly after [18F]PSMA administration. The procedure then includes a 30 minutes break, followed by a last dynamic scan 90-120 minutes post injection. Accuracy of blood and plasma activity concentration, plasma metabolite measurements derived from arterial and venous samples as well as the reliability of using Image Derived Input Functions (IDIF) for quantification of [18F]PSMA kinetics will be tested.

Part B Following results of Part A, a scanning protocol consisting of a WB PET-CT after administration of [18F]PSMA will be performed. This procedure will be repeated within a maximum of 7 days.

Contacts

Public
Bernard Jansen
De Boelelaan 1117

Amsterdam 1081 HV
The Netherlands
+31-20-44446033
Scientific
Bernard Jansen
De Boelelaan 1117

Amsterdam 1081 HV
The Netherlands
+31-20-44446033

Eligibility criteria

Inclusion criteria

Part A

• Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastases

• Written informed consent

• Per patient at least two metastases in the thorax, 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)

• Diameter of one thoracic metastasis at least ≥ 1.5 cm (to minimize partial volume effects)

• Patients able to remain supine for 90 minutes in the PET-CT scanner

Part B

• Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastasis

• Written informed consent

• At least one metastasis (not necessarily thoracic) 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 (maximum) 90 minutes in the PET-CT scanner

Exclusion criteria

• Claustrophobia (part A and B)

• Multiple malignancies (part A and B)

• Participation in part A (part B)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6302
NTR-old	NTR6477
Other	Protocol Version 1.4 : VUmc

Study results