Optimisation of [68Ga] PSMA-11 PET/CT Imaging Protocol for localizing primary prostate cancer prior to radical prostatectomy

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

Summary

ID

NL-OMON43099

Source
ToetsingOnline

Brief title
Optimisation of [68]Ga-PSMA PET/CT protocol

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
first diagnosis, Prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: PET/CT, Primairy localised, Prostate cancer, PSMA

Outcome measures

Primary outcome

This study aims to determine the optimal kinetic model for 68Ga-PSMA uptake and to design a simplified quantitative model for tracer uptake (Part A).To establish the ideal timing of performing the whole body 68Ga-PSMA PET after administration of the radiotracer and to determine the optimal (quantitative) method for measuring 68Ga-PSMA uptake (Part A).

To determine whether it is feasible to exactly identify and localize the tumour within the prostate (Part A and B).

To study test-retest characteristics of 68Ga PSMA PET (Part B).

Secondary outcome

Furthermore, we want to determine the test-retest variability of the simplified quantitative model for 68Ga-PSMA that follows from part A (Part B). Secondary, we want to assess if 68Ga-PSMA PET/CT is able to localize and identify tumour tissue within the prostate, compared to mpMRI (Part A and B).

- Quantify 68Ga-PSMA uptake kinetics in tumour lesions.

- Comparison of 68Ga-PSMA PET (study visit) versus mpMRI (standard of care) regarding to tumour localization within the prostate.

Study description

Background summary

Prostate Specific Membrane Antigen (PSMA) is a epithelial cell surface trans-membrane protein. It is overexpressed in prostate cancer, but is also present in normal prostate cells, kidney, liver, salivary glands and upper large intestine. This protein can be labelled to different radionuclides, but most experience has been gathered with Gallium-68 (68Ga). The PSMA-inhibitor Glu-NH-CO-NHLys-(Ahx)-[68Ga(HBED-CC)] (68Ga-PSMA-11) was developed by the group of Afshar-Oromieh et al. in Heidelberg. Numerous studies in recurrent prostate cancer showed that PSMA PET/CT is superior to an older phospholipid derivate used in molecular imaging of prostate cancer; choline PET/CT. Although the first studies on PSMA PET/CT focused on recurrent prostate cancer, PSMA PET/CT(or MRI) is currently also used and studied in primary prostate cancer, with encouraging results. There are a lot of treatment methods available for patients with prostate cancer, ideally we would be able to monitor treatment response. Because PET/CT images both in vivo anatomical and metabolic information it can be the ideal imaging bio-marker. To serve as a biomarker, 68 Ga-PSMA PET/CT results have to be quantified. The primary goal of this study is to find the optimal model that fits the pharmacokinetics of 68 Ga-PSMA-11 PET/CT, so that simplified quantification methods can be found. It is important to validate simplified quantification mehods, as there is need to monitor disease and treatment response in-vivo, without invasive treatment, to make a tailored individualized therapy approach possible in prostate cancer. The validity and repeatability of the simplified quantification method will then be tested as secondary aim of this study. Because this study will be performed in patients who will undergo prostatectomy, we will also be able to compare the properties of 68 Ga-PSMA PET/CT to localize intraprostatetic cancer lesions to the current standard, multi-parameter Magnetic Resonance Imaging (mpMRI). According to a recent meta-analysis, MRI has a high specificity for localizing primary prostate cancer. However, a relative poor sensitivity was shown, especially for extrapostatic growth.

Study objective

The primary objective is to determine the optimal pharmacokinetic model of 68Ga-PSMA PET/CT, so 68Ga-PSMA PET/CT results can be quantified in prostate cancer.
The secondary objectives are to determine whether the optimal kinetic model of 68Ga-PSMA PET/CT is valid (by a repeatability test) and to see if 68Ga-PSMA PET/CT could be a feasible method to exactly localize the tumour within the prostate.

Study design

A monocenter, prospective observational study in 20 patients with primary prostate cancer. The study consists of two parts: part A, to determine the tracer kinetic properties and the optimal pharmacokinetic model to quantify and identify 68Ga-PSMA uptake, to assess which (perfusion independent) pharmacokinetic parameter best reflects presence of tumour and to validate simplified (quantitative) metrics that can be used in a clinical setting. The optimal model and quantitative analysis will be used in part B, to determine whether 68Ga-PSMA is able to exactly and repeatedly localize the tumour within the prostate, prior to radical prostatectomy. Patients participate in either part A or part B, never both.

A. In the first part, both PSMA (68Ga-PSMA) uptake and perfusion (H215O) will be measured quantitatively. Eight patients will be injected with two tracers: H215O and 68Ga-PSMA followed by dynamic scans of one bed position, namely the pelvis. Accuracy of blood and plasma activity concentrations, plasma metabolite measurements derived from arterial and venous samples as well the reliability of using Image Derived Input Functions (IDIF) for quantification of 68Ga-PSMA kinetics will be tested.

B. In the second step of the protocol, depending on the obtained validation in part A, the clinically feasible imaging procedure will be used in 12 other patients, e.g using a simplified 68Ga-PSMA PET-CT imaging study, in aim to visualize the location of the primary tumor within the prostate. Repeat PSMA PET/CT scanning will be performed in these 12 patients, to evaluate test-retest repeatability in tumor tracer uptake and localization.

Study burden and risks

For this imaging study patients have to make 1 (part A) or 2 (part B) extra visits to the clinic to receive tracer injection and to undergo 2 PET scans. Part A implements a radiation burden of 4.1 mSv, part B of 9.4 mSv. See appendix K6.
For PET imaging in part A, patients will be given a radial artery cannula, which will give minor discomfort and with possible side effects of hematoma and infection. Based on previous research, we consider that the risks are negligible and the burden will be minimal. A total of 250 ml blood will be taken during the scans of part A. Patients that use anticoagulants are excluded from part A of the study to minimize risks.

Radiation burden 68Ga-PSMA PET = 3.2 mSv. Radiation burden 15O-H2O PET = 0.4 mSv.
Part A: low-dose CT scan one bed position (21cm) of the pelvis with a total radiation burden 0.5 mSv. Part A : Etotal = 4.1mSv

Part B: Patients will undergo two whole-body 68Ga-PSMA PET/CT scans.
For attenuation correction there will be a low-dose CT scan gemaakt from head to halfway femur with a radiation burden of 1.5 mSv. Part B: Etotal = 9.4 mSv

According to ICRP(International Commission on Radiological Protection) 62, This study falls under category 2B.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male aged 18 years or older
* Ability to provide signed informed consent and willingness to comply with protocol requirements.
* Biopsy confirmed presence of adenocarcinoma of the prostate gland
* Planned/already executed mpMRI (standard of care).
* Planned for radical prostatectomy (standard of care).

Exclusion criteria

* Have any medical condition or other circumstances that, in the opinion of the investigator, would significantly decrease obtaining reliable data, achieving study objectives, or completing the study. (part A and B)
* Have a contraindication for mpMRI. (part A and B)
* Will not undergo a radical prostatectomy. (part A and B)
* Claustrophobia (part A and B)
* Multiple malignancies (part A and B)
* Anticoagulant therapy (part A)
* Obese (>120 kg) (part A)
* Have undergone a transurethral resection of prostate in the past (part A and 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:	Recruitment stopped
Start date (anticipated):	03-09-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	68-Ga PSMA-11
Generic name:	Glu-NH-CO-NH-LYS-(ahx)-[68Ga(HBED-CC)]
Product type:	Medicine
Brand name:	H2[15]O

Generic name:	Hydrogen [15O]

Ethics review

Approved WMO Date:	26-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2016-002485-31-NL
CCMO	NL58936.042.16