Intra-arterial injection of 18F-DCFPyL for the evaluation of Prostate Cancer with Complete Temporary Embolization

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Primary Objective: * To evaluate the ability to concentrate the radiotracer within the prostate gland improving the evaluation of the primary prostate tumor. Secondary Objective(s): * To evaluate the PET/CT imaging characteristics of transcatheter,...

Ethical review	Not approved
Status	Will not start
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON48236

Source
ToetsingOnline

Brief title
18F-DCFPyL PET/CT with vascular embolization in Prostate Cancer

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Antoni van Leeuwenhoek

Intervention

Keyword: 18F-DCFPyL, Intra-arterial, PET/CT, Prostate Cancer

Outcome measures

Primary outcome

* Increase of the amount of tracer in the prostate gland by 20% compared to systemic administration evaluated via the radiation within the blood draws or measured on PET/CT images compared to systemic PET

* Improved PET/CT imaging quality and accuracy of detecting the primary prostate tumor within the prostate gland or local lymph node identification after local administration compared to standard of care systemic

Secondary outcome

* Multi-parametric MRI of the prostate to evaluate the changes to the vascularity after the procedure with comparison to baseline pre-PET tracer administration MRI imaging findings to verify normal profusion after the arterial administration.

Study description

Background summary

For patients with local, advanced, or recurrent PCa, there is a great need for the development and implementation of improved imaging modalities that can help to identify the location of the primary PCa tumor in the prostate, and location of local-regional disease or distant spread with minimal toxicity.
A peptide small molecule which specifically targets Prostate-Specific Membrane Antigen (PSMA) trans-membrane antigen which is upregulated on PCa cells has been developed and used clinically for accurate whole body positron emission tomography (PET) imaging. The systemic administration of this PSMA targeting

agent has yielded tremendous clinical success in both imaging and treating PCa due to its high tumor sensitivity and rapid pharmacokinetic elimination. However, one limitation is in visualizing primary tumors in the prostate due to an inadequate tumor to background ratio.
From experience with the minimally invasive transcatheter treatment of liver tumors, we know that chemotherapy or radiation can be concentrated within a tumor via directed intra-arterial administration. This technique isolates the tumor from the systemic circulation, resulting in the concentration of therapeutic treatment with minimal to no risk of adverse events related to nontarget administration. It is hypothesized a similar procedure can be successfully utilized in the prostate for both imaging and treatment whereby a PSMA targeting radiopharmaceutical is directly delivered in an intra-arterial fashion with vascular embolization.

Study objective

Primary Objective:

* To evaluate the ability to concentrate the radiotracer within the prostate gland improving the evaluation of the primary prostate tumor.

Secondary Objective(s):

* To evaluate the PET/CT imaging characteristics of transcatheter, prostatic artery administered 18F-DCFPyL after complete temporary* vascular isolation of the prostate from the systemic vascularity.

* Assess the leak rate and systemic radiation dose when a PSMA PET tracer is delivered into the arterial circulation after temporary vascular isolation of the prostate from the systemic vascularity.

* To calculate the dosimetry of a directly arterially administered PET PSMA for both the systemic circulation (whole body, liver, spleen, kidneys, and bladder) and prostate gland after temporary vascular isolation of the prostate from the systemic vascularity

* To evaluate the changes to the prostate vascularity after temporary prostate artery embolization.

Study design

This is a proof of concept study of the direct intra-arterial administration via the prostate artery of an imaging tracer as a means to improve clinical imaging and act as a segregate for dosimetry prior to intra-arterial therapy. The systemic, intravenous administration of this radiotracer is a standard part of the normal clinical evaluation of patients with prostate cancer. The study

will be conducted at the Netherlands Cancer Institute (NKI), Amsterdam, The Netherlands. Duration of inclusion is estimated at 24 months to include the sufficient number of patients.

The two arms in this project are:
1) Local artery injection of the imaging tracer with no additional embolization
2) Temporary, complete prostate artery embolization (CPAE) with a bioresorbable particle for temporary blockade of vascular flow

Between 3-5 patients will be recruited for inclusion into each one of the two groups with potential maximum 10 patients included in the study.

Intervention

For the purpose of this study a catheter directed angiography of the prostate arteries will be performed and either CPAE with 50 um resorbable particle or direct arterial administration of radiotracer will be performed. Embolization group will subsequently be administered an intra-arterial (i.a.) injection of 18F-DCFPyL into the prostate artery. The second group is comprised of only direct arterial administration. After angiography a PET/CT and MRI will be made. Blood samples to evaluate the systemic radiation dose after administration will be obtained to identify prostate uptake and systemic nontarget radiation dose.
All included patients will continue be treated with standard of care therapy for PCa before, during, and after participation without any interruption of treatment

Study burden and risks

The patient will undergo an additional minimally invasive procedure consisting of an angiogram of the pelvis and prostate, this procedure uses radiation for imaging. The embolization is not permanent. The temporary embolization group will have the particles reabsorbed after 2 hours. No change in the available treatments or side effects related to the embolization are expected. The risks of this procedure are small and include damage to a vessel, bleeding, infection, kidney injury, and anaphylaxis, however these complications are extremely rare (e.g. less than 1-2%).
18F-DCFPyL PSMA PET is a commonly employed clinical radiotracer with an excellent safety profile and low radiation dose. The potential radiation dose that will be encounter by the prostate with complete absorption of the entire radiotracer dose within the prostate is safe and negligible, in this extreme case the radiation dose will have no effect on the prostate or surrounding pelvic organs.
Three additional blood draws will be required from the patients, the first will be via the indwelling vascular sheath immediately after infusion. Repeat blood draws will be obtained at one and two hours after the infusion.

After the procedure the patient will receive a PET/CT scan and a multi-parametric MRI. This is an out-patient procedure but the patient can elect to remain in the hospital overnight for observation.
Follow-up will be performed at the patients normal oncologic clinic appointment and requires no extra visits.

Systemic Intravenous administration of a PSMA PET tracer for prostate malignancies is an effective and safe imaging treatment, however, limitations exists in identifying the location of the primary cancer within the prostate gland due to a low tumor to background ratio and non-target uptake in adjacent organs such as the bladder. We hope to optimize the first-pass binding in PSMA positive tumors and limit systemic administration of radiotracer; thus decreasing the systemic dose and improving the imaging quality and clinical information that can be obtained from a PSMA PET/CT.
Potential benefits: Systemic Intravenous administration of a PSMA PET tracer for prostate malignancies is an effective and safe imaging treatment, however, limitations exists in identifying the location of the primary cancer within the prostate gland due to a low tumor to background ratio and nontarget uptake in adjacent organs such as the bladder. We hope to optimize the first-pass binding in PSMA positive tumors and limit systemic administration of radiotracer; thus decreasing the systemic dose and improving the imaging quality and clinical information that can be obtained from a PSMA PET/CT.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age >18 years
* Confirmed histological diagnosis of PCa;
* The Eastern Cooperative Oncology Group (ECOG) performance status * 2
* Received a baseline multi-parametric MRI and PSMA PET/CT * 6 month prior to intra-arterial treatment
* Demonstrate adequate hematologic and organ function, defined by the following laboratory results.
* All screening laboratory tests should be performed within 30 days prior to the procedure:
Absolute neutrophil count (ANC) * 1500 cells/*L
Platelet count * 100.000/*L
Hemoglobin * 5.6 mmol/L
AST and ALT * 3
Serum bilirubin * 1.5
Serum Creatinine * 1.5 x ULN OR measured of calculated creatinine clearance (GFR can also be used in place of creatinine or CrCl) * 40 mL/min for subject with creatinine levels
* Signed Informed Consent Form

Exclusion criteria

* A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Concomitant malignancies, please describe
* Severe allergy for iodine based contrast agents
* Prior treatments with brachytherapy or prostatectomy.
. Inability to undergo intra-aterial procedure secondary to vascular abnormalities
. Body weight over 150kg
. Severe allergy for I.V. contrast used in angiography

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	18F-DCFPyL
Generic name:	18F-DCFPyL

Ethics review

Not approved

Date:	12-12-2019
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	EUCTR2019-000539-16-NL
CCMO	NL69175.031.19