Prostatic Artery Injection vs Intra-Venous Injectin of 18F-DCFPyL to evaluate treatment strategy in Prostate cancer

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Primary Objective: • To evaluate the ability to concentrate the radiotracer in prostatic cancer lesions (with respect to accumulation in background tissues) by prostatic artery injection (PAI), especially within the prostate gland compared to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON49732

Source
ToetsingOnline

Brief title
PAI vs IV injection of 18F-DCFPyL PET/CT in Prostate Cancer

Condition

- Renal and urinary tract neoplasms malignant and unspecified

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, Prostate cancer, Prostatic Arteric Injection

Outcome measures

Primary outcome

• Increase the ratio target (prostate cancer lesion) vs. non-target to background (gluteal muscle and blood pool) accumulation by 30% with intra-arterial compared to systemic administration evaluated on PET/CT images using SUV(mean and/ or max)

Secondary outcome

• Lower the ratio target vs. non-target tissue accumulation, especially to the kidneys and salivary glands, by 30% compared to systemic administration evaluated via the radiation measured on PET/CT images SUV(mean and/ or max).

• Detection of new lesions in the primary prostate tumor within the prostate gland or local lymph node identification / micro metastasis after local administration compared to standard of care systemic administration

• Registration on the number and severity of adverse events (AEs, SAEs and SUSARs) with intra-arterial compared to systemic administration

• Evaluation of accumulation patterns on PET/CT in the prostate bed after intra-arterial compared to systemic administration derived by image-based heterogeneity parameters.

• Estimation of 177Lu-PSMA radiation dose using 18F-DCFPyL accumulation

patterns on PET/CT after intra-arterial vs. systemic administration.

Study description

Background summary

Prostate cancer (PCa) is the most common non-cutaneous neoplasm in men.For patients with local, advanced, or recurrent PCa, there is a great need for the development and implementation of new treatments that can help to identify and target the tumor cells.
In 2018 the *image of the year* at the SNMMI was a PSMA PET before and after lutetium-177 PSMA617 theranostics in 8 patients with metastatic prostate cancer who exhausted standard therapeutic options with extraordinary results.
Currently the phase III Vision trial is trying to prove scientifically that this should be standard care in patients with local or 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 up regulated 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 tumour sensitivity and rapid pharmacokinetic elimination.
However, one limitation is the uptake of the tracer by non-target tissue.
From experience with the minimally invasive transcatheter treatment of liver tumours, we know that chemotherapy or radiation can be concentrated within a tumour via directed intra-arterial administration. This technique isolates the tumour from the systemic circulation, resulting in the concentration of therapeutic treatment with minimal to no risk of adverse events related to non-target 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 within the prostatic artery. This minimally invasive procedure will increase the local concentration of the tracer and allow the tracer to interact with the providing a superior first pass uptake for the radiopharmaceutical. Improving the tumour to background ratio for superior imaging and eventually allowing the substitution of a treatment radionuclide for this procedures application as a means of localized treatment. Our study aims to determine the feasibility with intra-arterial injection of 18F-DCFPyL PSMA as a means to concentration of the tracer within the prostate gland and (loco) regional lymph nodes and lower the uptake in non-target tissue. And at last to see whether there are new tumour sites within the prostate or not identified lymph nodes/

micro metastasis.

Study objective

Primary Objective:
• To evaluate the ability to concentrate the radiotracer in prostatic cancer lesions (with respect to accumulation in background tissues) by prostatic artery injection (PAI), especially within the prostate gland compared to standard systemic intra-venous (IV) administration.

Secondary Objectives:
• To evaluate the PET/CT targeting characteristics of prostatic artery injection (PAI) with 18F-DCFPyL to non-target tissue; especially to the kidneys and salivary glands in comparison with IV administration .

• Correlation of 18F-DCFPyL uptake in prostatic lesions and lymph node after IV and PAI injections with standard multi-parametric MRI

• To evaluate adverse events (AEs, SAEs and SUSARs) after IV and PAI administration of 18F-DCFPyL

• Show the difference in accumulation pattern for IA vs IV administration of 18F-DCFPyL in the prostate bed.

• Ability to calculate the optimal therapeutic radiation dose for 177Lu-PSMA therapy

Study design

Phase IIb proof of concept study with one cohort.

Intervention

For this study a catheter directed angiography of the prostate arteries will be performed in each patient. Direct arterial administration of radiotracer into the vascular bed of the prostate gland via the prostate artery (both sides). There will be no changes to the vascularity of the prostate. After the angiography a PET/CT will be completed.

Study burden and risks

The patient has one extra visit to the hospital as an outpatient procedure for 6 hrs. There is no hospital stay required. The patient will undergo an additional minimally invasive procedure consisting of an angiogram of the pelvis and prostate, this procedure uses radiation for imaging of 16-17mSv. No change in the available treatments or side effects related to the PAI 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 is a commonly employed clinical radiotracer with an excellent safety profile and low radiation dose of 2-3 mSv. 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.
The patient will undergo a PET/CT scan after the angiography.

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

• Age >70 years
• Confirmed histological diagnosis of PCa
• All (T) (N) (M) stages
• The Eastern Cooperative Oncology Group (ECOG) performance status <= 2
• Received a baseline multi-parametric MRI and 18F-DCFPyL PET scan <= 6 month prior to inclusion in our study done in NKI-AVL
• 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:
o Absolute neutrophil count (ANC) >= 1500 cells/µL
o Platelet count >= 100.000/µL
o Hemoglobin >= 5.6 mmol/L
o AST and ALT <= 3 (x ULN)
o Serum bilirubin <= 1.5 (x ULN)
o 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

• History of concomitant malignancies
• Severe allergy for iodine-based contrast agents
• Prior treatments with brachytherapy or prostatectomy
• Inability to undergo intra-arterial procedure secondary to vascular abnormalities
• Body weight over 150 kg
• Severe allergy for I.V. contrast used in angiography

Study design

Design

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

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2021
Enrollment:	21
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	29-12-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-02-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-10-2022
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2020-001219-26-NL
CCMO	NL73434.031.20