Variation on PSMA Receptor Expression over time in prostate cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24248

Source
Nationaal Trial Register

Brief title
PRET

Health condition

Prostate cancer

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: This research is supported by KWF Kankerbestrijding and Technology Foundation STW, as part of their joint strategic research programme ‘Technology for Oncology’ (Grant number 15175).

Intervention

Outcome measures

Primary outcome

To obtain preliminary data on variability in PSMA expression by comparing prostate uptake on standard clinical 68Ga-PSMA PET/CT with 68Ga-PSMA PET/CT performed 4 weeks later.

Secondary outcome

Dynamic imaging will be performed in order to get insight when the uptake in the prostate is visible

Study description

Background summary

Prostate cancer is the third most common cancer in Europe and is still the leading cancer among men in the Netherlands with over 13,000 men diagnosed each year. 68-Gallium Prostate Specific Membrane Antigen (68Ga-PSMA) is an emerging imaging agent that already has been widely proven as a highly effective agent for restaging PCa cells, but also holds enormous potential for initial staging and image guided surgery. During surgery, 68Ga-PSMA can potentially be used for the assessment of resection margins based on Cerenkov Light emission. The interval between initial staging and subsequent prostatectomy surgery, however, ranges from 4 to 6 weeks. Since little is known about the PSMA expression over time without intervention, a study on this is required. If PSMA expression is equal between both scans, the inclusion and dose determination for image guided surgery can be based on the clinical 68Ga-PSMA PET/CT scan. In order to validate this, two PET scans will be performed in a test-retest setting in primary prostate cancer patients. Dynamic imaging will be performed in order to get insight when uptake in the prostate is visible. Subsequently this will be used also to establish the ideal timing of surgery after injection.The objective of this study is to obtain preliminary data on variability in PSMA expression by comparing the tracer uptake on conventional clinical 68Ga-PSMA PET/CT with an additional 68Ga-PSMA PET/CT (4 weeks later) within primary prostate cancer patients. Dynamic imaging will be performed in 5 patients in order to get insight when uptake in the prostate is visible.

Study objective

We expect that the second measurement will be different from the first measurement by no more than 10%.

Study design

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Proven primary prostate carcinoma
- >18 years
- Good knowledge of Dutch language
- Written informed consent
- Underwent a pelvic MRI-scan
- Eligible for 68Ga-PSMA PET/CT
- Lesion bigger than 10mm on MRI, to minimize partial volume effects

Exclusion criteria

Contraindications for a PET/CT scan.
- Therapy scheduled between scans
- No PSMA expression in the primary tumor on the first PET scan, excluded for the second scan

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2018
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46835
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8263
CCMO	NL64593.031.18
OMON	NL-OMON46835

Study results