Variation on PSMA receptor expression over time in prostate cancer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON46835

Source
ToetsingOnline

Brief title
PRET - PSMA Receptor Expression over Time

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NWO domain TTW/KWF,Lightpoint Medical Ltd (vergoeding zit in de KWF grant),Philips

Intervention

Keyword: Ga-68 PSMA, PET/CT scan, PSMA-expression, Test-retest

Outcome measures

Primary outcome

The main study endpoint is to evaluate the PSMA expression variation at 4 week

intervals.

Secondary outcome

The secondary endpoint is to determine the optimal time between 68Ga-PSMA

injection and prostate surgery for future image-guided surgery.

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 into the optimal scan time. Subsequently this will be used also to establish the ideal timing of surgery after injection.

Study objective

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 order to get insight into the most ideal scan time.

Study design

This is a prospective observational feasibility study

The aim is to obtain preliminary data on variability in PSMA receptor expression by comparing uptake within prostate on standard clinical PET/CT with pre-operative PSMA PET/CT, 4 weeks later.
Primary prostate cancer patients will be included, based upon their MRI, before their first PET scan. Patients will undergo another PSMA PET-scan within 4 weeks after their standard diagnostic PSMA-PET scan. The protocol for this scan is equal to standard diagnostic PSMA-PET scan. A PET combined with low dose-CT for attenuation correction and anatomical correlation will be acquired at approximately 45 minutes after administration of 68Ga-PSMA.

With 5 patients a dynamic PET/CT-scan (dPET/CT) will be made up to 35 minutes after administration. Where after a normal skull base to mid femurPET/CT is made. Within the scans, the patient is requested to void, to improve visualisation of the prostate on the PET scan.

Study burden and risks

The patients included in this study have an additional radiation exposure, since they need to undergo an additional PET-scan prior to surgery, after injection of the radiotracer 68Ga-PSMA. This will approximatly be 6mSv. The 5 patients for the dynamic scans, will have an additional exposure of 3mSv. The total exposure llies within the acceptable diagnostic exposure range.

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

primaire prostate cancer patients, written informed concent, tumour larger then 1cm, eligible for PET/CT (cT3/Gleason score >7/ PSA >20 ng/mL)

Exclusion criteria

contra-indications for PET/CT scan, therapy scheduled between scans, no PSMA expression on first PET-scan (exclusion for second scan)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2019

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2018
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

ID: 24248
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64593.031.18
OMON	NL-OMON24248