PSMA Detect

Published: 11-02-2025
Last updated: 22-05-2025

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

Summary

ID

NL-OMON57497

Source
Onderzoeksportaal

Brief title
PSMA Detect

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: Antonius Onderzoeksfonds

Intervention

- Intervention with ionizing radiation

Explanation

N.a.

Outcome measures

Primary outcome

Detection rates of ISUP GG≥2 PCa in target biopsies of PSMA PET/CT lesions, which were not detected, by systematic biopsies.

Secondary outcome

- Detection rates of ISUP GG≥2 PCa in systematic biopsies in case of negative or equivocal MRI and PSMA PET/CT.
- Detection rates of ISUP GG≥2 PCa in systematic biopsies and negative or ISUP GG 1 result of PSMA lesion target biopsies.
- Level of SUVmax in correlation with with ISUP GG ≥2 PCa.
- Detection of clinically insignificant PCa (ISUP GG 1) in both PSMA-guided target biopsies and in systematic biopsies
- Percentage of change in management in case of upgrading based on PSMA-guided biopsies.
- Cost-effectiveness of an extra PSMA PET/CT scan.

Study description

Background summary

In the current biopsy strategy based on MRI imaging of the prostate, approximately 10% of significant prostate cancers (sPCa) are missed. The addition of a PSMA PET/CT scan in a select group of patients may potentially detect these missed sPCa cases. Data from the PASPoRT study, conducted at our institution, supports the hypothesis that PSMA PET/CT can provide added diagnostic value. This study focused on patients with low-risk prostate cancer. Following the addition of PSMA PET/CT and targeted biopsies of suspicious PSMA lesions, 9% of patients experienced upstaging. In a subgroup with a PSA density (PSA divided by prostate volume) ≥ 0.15, the rate of upstaging was as high as 35%.
In the present study, we aim to evaluate the detection of sPCa using an additional PSMA PET/CT scan in men with a negative or equivocal MRI (PIRADS 1-3) scan but a high suspicion of sPCa due to elevated PSA density.

Study objective

The primary objective of this study is to evaluate the added value of PSMA PET/CT and PSMA-targeted biopsies of PSMA-avid lesions in detecting ISUP GG ≥ 2 prostate cancer in patients with a negative or equivocal MRI (PIRADS 1-3) and a PSA density of ≥0.20 ng/ml/cm^3.
Additionally, we aim to assess the number of ISUP GG ≥ 2 cases detected through systematic

biopsies that are not identified by PSMA-targeted biopsies or in the absence of a PSMA-avid lesion. This evaluation seeks to determine whether systematic biopsies are necessary when no PSMA-avid lesion is present for targeted biopsy.

Study design

Prospective observational cohort study

Intervention

Patients with a high suspicion of prostate cancer (PCa) based on elevated PSA levels and/or abnormal digital rectal examination(DRE), and a prostate-specific antigen density (PSAD) ≥ 0.20 ng/ml/cm³, but with a negative or equivocal prostate MRI result(PIRADS 1-3) will undergo an extra PSMA PET/CT.

Study burden and risks

Participation in the study may allow for earlier detection of more aggressive histology. In addition to standard care (including: MRIscan, systematic transperineal biopsies, targeted biopsies of MRI lesions), a PSMA-PET/CT scan will be performed. The PSMA-PETscan will require an extra visit, iv drip and small radiation burden. If there is a visible lesion on PSMA PET/CT, an extra target biopsy will be performed with a potential higher risk of complication: hematospermia, hematuria, infection, fever, pain). The risk of fever and infection is nihil, due to the transperineal biopsy technique that will be used.

Contacts

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Trial sites

Trial sites in the Netherlands

St. Antonius Ziekenhuis
Target size: 50

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men aged > 18 years old
- PSA 3-20 ng/ml
- Negative or equivocal MRI (PIRADS 1-3)
- PSAD ≥0.20 ng/ml/cm3, which should be measured with at least two PSA results (for example one of the generalpractitioner and one of the urologist)
- Mentally competent and understanding of benefits and potential burden of the study.
- Written and signed informed consent.
- Willing to undergo study protocol (systemic biopsies plus target biopsies of a lesion visible on PSMA PET/CT)

Exclusion criteria

- PSA > 20 ng/ml
- Men who have previously undergone a prostate biopsy
- Men who have a prior PCa diagnosis
- Using any (anti-)hormonal therapy
- Not fulfilling inclusion criteria
- Inability to undergo MRI (i.e., claustrophobia, metal implants)
- Inability to undergo PSMA PET/CT (i.e., allergic reaction to 68Ga-PSMA or other contrast fluids, claustrophobia)

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	50
Duration:	6 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	07-04-2025
Application type:	First submission
Review commission:	MEC-U

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
Research portal	NL-009325