# PSMA in Active Surveillance for PRostate cancer Trial

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON28271

**Source**
Nationaal Trial Register

**Brief title**
PASPoRT

**Health condition**

Prostate cancer

### Sponsors and support

**Primary sponsor:** St Antonius Hospital Research Fund
**Source(s) of monetary or material Support:** St Antonius Hospital Research Fund

### Intervention

### Outcome measures

**Primary outcome**

- Number of and characteristics of PSMA lesions visualized within the prostate gland.
- Histology (‘Gleason score’) of targeted biopsies of PSMA visualized lesions, when compared to previous histology.

**Secondary outcome**

- To assess the association between MRI findings in the prostate and local PSMA visualized lesions.
- To assess change of management due to PSMA-PET/CT findings and targeted biopsies.
- To analyse performance of PSMA lesions targeted prostate biopsies when compared to previously performed (regarding tumor length, core involvement):
- Systematic prostate biopsies
- MRI lesion targeted biopsies.
- Time to deferred active therapy versus historical cohort (hypothesis: Increased acceptance).
- Time to deferred active therapy versus historical cohort (hypothesis: Increased adherence).

# Study description

**Background summary**

Rationale
Expectant management (‘active surveillance’) for low risk prostate cancer has become an important part of prostate cancer management. Active surveillance aims to decrease overtreatment by avoiding or postponing radical therapy of tumours that are presumed to have an indolent natural course, even when remaining untreated. Risk stratification of prostate cancer, using clinical parameters and MRI, in order to decide for active surveillance versus active therapy, is imperfect.
Objective
To introduce 68Ga-PSMA-PET/CT scanning in risk stratification of prostate cancer patients assumed to be suitable for active surveillance.
Study design
Prospective cohort study.
Study population
Patients >18 yrs with newly diagnosed, histologically proven, low risk (using clinical parameters and MRI) prostate cancer patients, eligible for active surveillance according to the currently applied criteria.
Intervention
PSMA-PET/CT scan of the prostate and pelvis, targeted prostate biopsies of lesions not previously visualized and targeted by biopsies.
Main study parameters/endpoints:
- Primary: Diagnostic accuracy of PSMA-PET/CT in: 1 - Visualization of lesions in the prostate. 2 - Histology (‘Gleason score’) of targeted biopsies of PSMA visualized lesions
- Secondary: 1 - Association between prostate MRI scan and PSMA-PET/CT visualized lesions. 2 - The performance of PSMA targeted lesions when compared to: Systematic biopsies and MRI lesion targeted biopsies. 3 - Percentage of patients choosing expectant management with MRI + PSMA-PET/CT selection. 4 - Time to deferred active therapy versus historical cohort.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness
In addition to standard care (including: MRI scan, systematic transrectal biopsies, targeted

biopsies of MRI lesions), a PSMA-PET/CT scan will be performed. The PSMA-PET scan will require: Extra visit and iv drip, small radiation burden. In the case of PSMA lesions not previously visualized on MRI: Extra set of transrectal targeted prostate biopsies in outpatient setting (risk of complications: hematospermia, hematuria, rectal bleeding, infection, fever (2-3%), pain). Participation in the study may allow for earlier detection of more aggressive histology.

### Study objective

PSMA PET scanning and targeted prostate biopsies of lesions not previously visualized, improves risk stratification of low risk prostate cancer, and selection for active surveillance.

### Study design

Start study 1/7/2019

### Intervention

PSMA PET scan en targeted prostate biopsies

## Contacts

**Public**
St Antonius Ziekenhuis
Roderick van den Bergh

+31623456800
**Scientific**
St Antonius Ziekenhuis
Roderick van den Bergh

+31623456800

## Eligibility criteria

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Men >18 years of age
- Mentally competent and understanding of benefits and potential burden of the study.

- Written informed consent.
- Life expectancy >10 years
- Histological confirmed diagnosis adenocarcinoma prostate.
- Suitable for radical treatment
- Willing to start active surveillance
- Underwent systematic biopsies of the prostate, had at least biparametric MRI of the prostate, underwent MRI lesion targeted biopsy in case of visualized lesions (cognitive, software-based, or MRI-in bore fusion of images with transrectal ultrasound)
- Currently applied criteria for active surveillance:
- PSA <20.0 ng/ml
- PSA density <0.2 ng/ml/ml
- Clinical and radiological stage T1c-2 Nx-0 Mx-0
- Capsular contact ≤6 mm on MRI
- If maximal Gleason score 3+3=6
- in ≤33% of systematic biopsy cores (no limit number of positive targeted biopsies)
- no limit number of MRI lesions
- no limit diameter MRI lesions
- If maximal Gleason score 3+4=7
- in maximal 1 systematic biopsy core (no limit number of positive targeted biopsies), other systematic biopsy cores allowed to be positive, as long as total number systematic biopsies <33%
- maximal one MRI lesion, ipsilateral to Gleason 3+4=7 biopsy core (indicating that MRI visualized lesion is actually the highest grade lesion)
- maximal lesion diameter <15 mm

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Very low risk disease defined as non-palpable, non MRI visualized, 1 systematic biopsy only, Gleason 6, PSA less than 10.0 prostate cancer.
- Clinical or radiological suggestion of T3 disease.
- Gleason score 4+3=7 or higher / less favorable, in any biopsy core.
- Gleason score 3+4=7 in more than 1 systematic biopsy core, or in a systematic biopsy core contralateral to the visualized MRI lesions.
- More than 1 MRI lesion and detection of Gleason 3+4=7.
- Histological cribriform growth pattern
- Histological (intra)ductal carcinoma
- Concomitant malignancy (except from BCC).
- Contra-indications for, or unwillingness to undergo MRI (such as pacemaker, claustrophobia) or PSMA PET-CT.
- History of prior diagnosed or treated PCa.
- Any unrelated illness (e.g. active infection, inflammation or laboratory abnormalities) that in the judgment of the investigator will significantly affect patient’s clinical status.

# Study design

## Design

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|---|---|
| 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: | Pending |
| Start date (anticipated): | 01-07-2019 |
| Enrollment: | 141 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 54856
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7743 |
| CCMO | NL69880.100.20 |
| OMON | NL-OMON54856 |

# Study results