# Use of PSMA-PET scanning in selection for active surveillance for low risk prostate cancer

Published: 24-03-2020
Last updated: 19-03-2025

To introduce 68Ga-PSMA-PET/CT scanning in risk stratification of prostate cancer patients assumed to be suitable for active surveillance.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Reproductive neoplasms male malignant and unspecified |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON54856

**Source**
ToetsingOnline

**Brief title**
PSMA in Active Surveillance for PRostate cancer Trial
PASPoRT

### Condition

- Reproductive neoplasms male malignant and unspecified

**Synonym**
prostaatkanker

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis
**Source(s) of monetary or material Support:** Antonius onderzoeksfonds

## Intervention

**Keyword:** Active Surveillance, MRI, Prostate Cancer, PSMA

## Outcome measures

### Primary outcome

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 outcome

- Visualization of MRI lesions in the prostate on PSMA.

- To assess the association between MRI findings in the prostate and local PSMA visualized lesions.

- To analyse the performance of PSMA lesions targeted prostate biopsies when compared to previously performed:

- 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).

- Determining the value of a follow up PSMA scan in detecting disease progression versus the standard of care.

# Study description

### Background summary

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.

### Study 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 burden and risks

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.

## Contacts

**Public**
Sint Antonius Ziekenhuis

Westerdijk 18m
Utrecht 3513 EW
NL
**Scientific**
Sint Antonius Ziekenhuis

Westerdijk 18m
Utrecht 3513 EW
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion 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

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 01-06-2020 |
| Enrollment: | 141 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | 68-Gallium-PSMA |
| Generic name: | 68-Gallium-PSMA |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 10-04-2020 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 30-12-2021 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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: 28271
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2019-004667-51-NL |
| CCMO | NL69880.100.20 |
| OMON | NL-OMON28271 |