# Multi-institutional Evaluation of the Cost-effectiveness of PSMA-PET/CT for the Detection of Pelvic Lymph Node Invasion in Newly Diagnosed Prostate Cancer Patients

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1. In patients with clinically non-metastasized prostate cancer (M0), performing ePLND solely in those who are node-positive (N1) on PSMA PET/CT setting results in: a. relatively lower healthcare costs, lower complication rates and less disease...

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24993

**Bron**
NTR

**Verkorte titel**
PSMA-Select

**Aandoening**

Prostate Cancer

### Ondersteuning

**Primaire sponsor:** Canisius Wilhelmina Hospital (CWZ)
**Overige ondersteuning:** ZonMW

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Biochemical recurrence rate within two years after surgery, defined as a PSA > 0.2 ng/ml.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale
To determine de lymph node status in men with prostate cancer (PCa) undergoing radical prostatectomy, an extended pelvic lymph node dissection (ePLND) is advocated by the prevailing guidelines. However, ePLND is a potential harmful and an expensive surgical procedure. Indication for ePLND is based on the risk of lymph node invasion (LNI) assessed by a nomogram. With the introduction of the PSMA-PET/CT scan, staging of PCa has improved substantially compared to conventional CT and bone scan. Although PSMA-PET/CT can detect LNI in an early stage, it is unclear whether it can serve also as an adequate selection tool for the indication of ePLND in patients with newly diagnosed localized or locally advanced PCa.

Objective
To determine if the use of Prostate-Specific Membrane Antigen Positron Emission Computer Tomography (PSMA PET/CT) as a selection tool for performing ePLND for PCa in the primary staging setting results in lower patient burden in terms of intervention-related complications and morbidity, with comparable disease prognosis, and therefore lower overall healthcare costs compared to the current European Guideline-recommended standard practice which includes performing ePLND in PCa patients who are candidates for radical prostatectomie with a nomogram-calculated lymph node involvement (LNI) risk >5%.

Study design
Randomized controlled trial.

Study population
Patients with newly-diagnosed PCa, without evidence of distant metastasis (any T, M0) determined on PSMA PET/CT, who are candidates for treatment with radical prostatectomy and ePLND based on a nomogram-calculated risk of LNI >5%.

Intervention
The PSMA selected indication for ePLND (intervention) is compared to the nomogram-based indication for ePLND, which is the standard of care according to the guideline on PCa of the European Urologic Association (EAU).

Main study parameters/endpoints
The main study outcome is the biochemical recurrence rate within two years after surgery, defined as a PSA > 0.2 ng/ml. Secondary outcomes include number of ePLNDs performed and

associated complications.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
The PSMA-PET/CT is a standard imaging tool in PCa patients. Potential benefits for the patients in the intervention group (PSMA –based indication forePLND) are, lower complication rates, less disease morbidity and possibility of ‘image guided surgery’ based PSMA images. There is a small increased chance of missing pathological lymph node metastases possibly resulting in biochemical recurrence that need salvage treatment. It is assumed that this results in comparable (non-inferior) biochemical recurrence rates, compared with performing standard ePLND in all patients with risk of LNI >5%.

**Doel van het onderzoek**

1. In patients with clinically non-metastasized prostate cancer (M0), performing ePLND solely in those who are node-positive (N1) on PSMA PET/CT setting results in:
a. relatively lower healthcare costs, lower complication rates and less disease morbidity
b. comparable (non-inferior) biochemical recurrence rates, compared with performing ePLND in all patients with risk of LNI >5%.
2. Lymph node metastases missed by PSMA PET/CT on primary staging have small tumor diameter (< 5mm), therefore, not resecting these nodes in the primary staging setting does not impair the patient’s prognosis since these can be safely treated, when necessary, in the salvage setting without compromising the patient’s long-term disease outcome.

**Onderzoeksopzet**

- Two years to assess biochemical recurrence rates.
- Five years following surgery to assess longer-term outcomes, aiming to extend follow-up to 15 years after surgery if additional funding becomes available.

**Onderzoeksproduct en/of interventie**

PSMA PET/CT based indication for ePLND:
1. Node-negative PSMA PET/CT [N0] and M0: do not perform ePLND
2. Node-positive PSMA PET/CT [N1] and M0: perform ePLND

# Contactpersonen

## Publiek

St. Antonius Ziekenhuis
Lieke Wever

0652742318

### Wetenschappelijk

St. Antonius Ziekenhuis
Lieke Wever

0652742318

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1.>18 years
2. Biopsy proven adenocarcinoma of the prostate
3. Indication for ePLND combined with robot assisted radical prostatectomy (RARP) (MSKCC nomogram >5%, if not applicable when only MRI targeted biopsies are positive, the Briganti nomogram will be used)
4. Suitable for robot-assisted ePLND and RARP
5. Mentally competent and understanding of benefits and potential burden of the study 5. Written informed consent
6. No known allergies for PSMA tracer.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. History of prior diagnosed or treated PCa
2. Known concomitant malignancies (except Basal Cell Carcinoma of the skin)
3.Unwillingness or inability to undergo PSMA PET/CT and/or ePLND and RARP
4. PSMA non-avid PCa (local tumor activity)
5. Presence of distant metastasis (M1)

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 13-12-2020 |
| Aantal proefpersonen: | 546 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 13-12-2020 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
| --- | --- |
| NTR-new | NL9118 |
| Ander register | MEC-U : R20.109 |

# Resultaten