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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24993

Source
Nationaal Trial Register

Brief title
PSMA-Select

Health condition

Prostate Cancer

Sponsors and support

Primary sponsor: Canisius Wilhelmina Hospital (CWZ)
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Total number of ePLNDs and PSMA PET/CTs performed and their intervention-related healthcare costs, costs of complication-related interventions and associated (prolonged) hospital stay
- Total nodes resected during ePLND and number of positive and negative nodes.
- Modification of ePLND template; resected nodes within and outside of the normal ePLND template
- Occurrence of pelvic lymph node metastasis and distant metastasis (visceral, bone, distant lymph nodes, pelvic lymph nodes) on PSMA-PET/CT during follow-up
- Initiation of salvage therapy
- Metastasis-free survival
- Hormone-therapy free survival
- Patient-reported outcome measures (EPIC-26)
- Quality of life (EQ-5D questionnaire)
- Medical consumption costs using the Medical Consumption Questionnaire (MCQ)
- Productivity losses using the productivity Cost Questionnaire (PCQ)
- Diagnostic accuracy measures

Study description

Background summary

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%.

Study objective

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.

Study design

- 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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-12-2020
Enrollment:	546
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	13-12-2020
Application type:	First submission

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
NTR-new	NL9118
Other	MEC-U : R20.109

Study results