A two-step study into the predicTive value of FluoR-18 PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT before PLND for lymph nodE staging in primary pRostate cancer

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18F-PSMA-1007 PET/CT and/or anti-3-[18F] FACBC PET/CT are not accurate diagnostic tools for detection of lymph node metastases, with a sensitivity less than 80%.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27349

Bron
NTR

Verkorte titel
TRACER

Aandoening

Primairy intermediate to high risk prostate cancer

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis Eindhoven
Overige ondersteuning: 18F-Fluciclovine will be delivered by Blue Earth Diagnostics
18F-PSMA will be delivered by Radboud Translational Medicine b.v.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient and lesion-based diagnostic accuracy of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT (sensitivity, specificity, PPV and NPV) in detection of lymph node metastases.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Prostate cancer (PCa) is the most common malignancy amongst men in Western countries. In order to select the most suitable treatment for patients diagnosed with PCa, it is important to stage accurately. Lymph node metastasis have a negative effect on the prognosis, and furthermore, they can be associated with systemic metastasis. This means it is key to accurately diagnose the presence of these lymph node metastasis. Diagnostic accuracy of conventional imaging modalities (e.g. bone scintigraphy, CT, MRI) for the detection of (lymph node) metastases however, proved to be limited.
To improve detection of metastases, it might be preferable to use other diagnostic imaging techniques.
Both 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT (also named 18F-Fluciclovine PET/CT) are currently mostly used to detect recurrence in treated PCa, while the diagnostic value in detecting lymph node metastasis in primary prostate cancer is not yet clear. The present study therefore aims to determine the diagnostic accuracy of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in initial staging of intermediate- to high-risk PCa, by comparing both techniques to each other and to pelvic lymph node dissection (PLND).

Objective: To evaluate diagnostic accuracy of PSMA-PET/CT and FACBC-PET/CT in detection of lymph node metastases in initial staging of intermediate- to high-risk PCa.

Study design: Prospective cohort study.

Study population: Newly diagnosed patients with intermediate- to high-risk PCa, considered candidates for extended pelvic lymph node dissection.

Intervention: PSMA-PET/CT and FACBC-PET/CT, prior to lymph node dissection (PLND)

Main study parameters/endpoints: Main study parameter is patient- and lesion-based diagnostic accuracy of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in detection of lymph node metastases. Secondary study parameters are (a) diagnostic performance of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in detection of distant metastases, (b) diagnostic performance of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in staging of the primary tumor in the prostate specimen, (c) detection rate of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT as a function of PSA level, nomogram risk and size of suspected lymph nodes, (d) change of management induced by 18F-PSMA-1007 PET/CT and

anti-3-[18F] FACBC PET/CT and (e) cost-associated with 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT as diagnostic modality additional to the regular diagnostic work-up versus pelvic lymph node dissection.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The included patients will undergo 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT prior to pelvic lymph node dissection. To conform to the current standard of care, patient would only undergo one PET/CT (18F-PSMA-1007 PET/CT). This means there is one extra study-related intervention (anti-3-[18F] FACBC PET/CT), leading to extra radiation exposure. Next to that, patients are required to read the patient information form, which will take approximately 15 minutes. The results of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in the diagnostic process of prostate cancer will presumably give us more information about the best way to detect lymph node and distant metastases in an early stage. Ascertaining presence of metastatic disease will be of added value for individual patients in this study to guide treatment. Hopefully, in the future PLND can be omitted in selected patients.

Doel van het onderzoek

18F-PSMA-1007 PET/CT and/or anti-3-[18F] FACBC PET/CT are not accurate diagnostic tools for detection of lymph node metastases, with a sensitivity less than 80%.

Onderzoeksopzet

18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT will be planned within 6 weeks before PLND. Definitive pathology will be analysed in the week after surgery. For the study, the scans and pathology will be analysed by blinded specialists and reported on drawn templates before it will be transfered to the data management system.
Definitive analyses will be performed after inclusion of the last patient.

Contactpersonen

Publiek

Catharina Ziekenhuis Eindhoven
Robert Hoekstra

+31402397040

Wetenschappelijk

Catharina Ziekenhuis Eindhoven
Robert Hoekstra

+31402397040

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Biopsy proven adenocarcinoma of the prostate;
2. Indication for (super)extended PLND (with or without (robot-assisted) laparoscopic prostatectomy), in intermediate and high risk patients (d'Ámico score) with an MSKCC >5% lymph node prediction;
3. Mentally competent and understanding of benefits and potential burden of the study;
4. Written informed consent;
5. Age ≥18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT, in combination with PLND.
4. Metastasis beyond pelvic region and/or bone metastasis. Patients with bone metastasis will not get a PLND, but will be included in the study for further follow-up.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-02-2021
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	NL9319
Ander register	MEC-U : R19.050

Resultaten