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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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55108

Source
ToetsingOnline

Brief title
TRACER Study

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal and urinary tract therapeutic procedures

Synonym
cancer of the prostate, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: -Radboud Translational Medicine B.V. Nijmegen;Nederland -Blue Earth Diagnostics;Ireland

Intervention

Keyword: FACBC, Lymphe node dissection, Prostate cancer, PSMA

Outcome measures

Primary outcome

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.

Secondary outcome

a. Detection rate of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT for the detection of distant (bone) metastases.

b. Diagnostic accuracy of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT in staging of the primary tumor in the radical prostatectomy specimen.

c. Diagnostic accuracy of 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT

for different risk groups (according to the d*Amico classification - see

chapter 5.1.3), nomogram risk scores, and the size of malignant lymph nodes.

d. Diagnostic performance of 18F-PSMA-1007 PET/CT versus anti-3-[18F] FACBC

PET/CT versus conventional imaging (MRI of the prostate) in detection of local

tumor site and metastases.

e. Change of management induced by 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC

PET/CT findings specifically.

f. Cost-effectiveness of 18F-PSMA-1007 PET/CT versus anti-3-[18F] FACBC PET/CT

for the detection of (regional) LNMs.

Study description

Background summary

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 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).

Study 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.

Intervention

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

Study burden and risks

The included patients will undergo 18F-PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT prior to pelvic lymph node dissection. Conform the standard of care, patient would only undergo one PET/CT. This means there is one extra study-related intervention, 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, and in the future possibly for all PCa patients

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
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.

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 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.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-09-2020
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	FluoR-18 PSMA-1007 PET/CT
Generic name:	F18 PSMA
Product type:	Medicine
Brand name:	FluoR-18 PSMA-1007 PET/CT and anti-3-[18F] FACBC PET/CT
Generic name:	FACBC

Ethics review

Approved WMO Date:	15-05-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-08-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-09-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-02-2021
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-004045-33-NL
CCMO	NL70759.100.19