

Individualisation of management with novel upfront therapies in newly diagnosed metastasized prostate cancer using (PSMA)PET/CT imaging

Published: 19-10-2021

Last updated: 05-04-2024

To assess the predictive value of early response measurements on PSMA-PET/CT for therapy success, defined as time to development of castration-resistant prostate cancer (CRPC), in order to personalize treatment choice.

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

Summary

ID

NL-OMON51925

Source

ToetsingOnline

Brief title

PET-MaN

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Genitourinary tract disorders NEC
- Prostatic disorders (excl infections and inflammations)

Synonym

Prostate cancer; Malignancy of the prostate

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Janssen-Cilag, St Antonius Ziekenhuis Onderzoeksfonds.

Intervention

Keyword: Metastastasis, Prostate cancer, PSMA-PET/CT, Upfront therapy

Outcome measures

Primary outcome

Primary parameter: Predictive value of early response on PSMA-PET/CT to upfront therapy, according to PERCIST criteria. Primary endpoint: Time to development of CRPC.

Secondary outcome

Secondary parameters: Predictive value of early response on PSMA-PET/CT to hormonal therapy; predictive value of baseline PSMA-PET/CT, analysis of response in different subgroups of patients: e.g. high versus low tumour load, high versus low PSA, high versus low Gleason score. Secondary endpoint: Time to initiation of second line therapy after castration-resistant disease has been found.

Study description

Background summary

Men, newly diagnosed with metastasized prostate cancer, who start on standard hormonal therapy, are additionally treated with either upfront chemotherapy or upfront extra androgen-receptor targeted agents (*ARTA*), as per guidelines* recommendations. The benefit in overall survival of these two options is similar, but important differences exist in patient-specific efficacy, costs, side-effects, and impact on quality of life. No predictive factors are

available to individualize treatment choice. Currently, a one-size-fits-all strategy with hormonal therapy plus chemotherapy is usually followed.

Study objective

To assess the predictive value of early response measurements on PSMA-PET/CT for therapy success, defined as time to development of castration-resistant prostate cancer (CRPC), in order to personalize treatment choice.

Study design

Prospective, single arm, open label, non-interventional, non-therapeutic observational cohort study.

Study burden and risks

Patients will be treated according to standard of care using hormonal therapy and ARTA, including baseline diagnostic PSMA-PET/CT. The timing of follow-up PSMA-PET/CT imaging however will be standardized, instead of at biochemical or clinical signs of disease progression: One PSMA-PET/CT will be performed after 2 months of hormonal therapy, one PSMA-PET/CT will be performed after 2 months of upfront therapy. Each PSMA-PET/CT scan will require: an extra visit (2-3 hours) and a limited radiation burden after intravenous injection of PSMA. The additional information from the standardized follow-up PSMA-PET/CT scans will not be used for clinical decision making.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
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 and signed informed consent.
- Histological confirmed diagnosis of adenocarcinoma of the prostate.
- Indicated to start on hormonal therapy (any LHRH agonist or antagonist).
- Indicated to start on upfront ARTA therapy (i.e. abiraterone or apalutamide).
- Any initial PSA.
- Any Gleason score.
- Any T-stage.
- Any N-stage.
- Stage M1 (any; M1a, M1b, and/or M1c).
- More than three (>3) metastatic lesions (any combination of either lymph node metastasis outside of pelvis, bone metastasis, or visceral metastasis), as seen on imaging (any combination of CT, MRI, skeletal scintigraphy, and/or (PSMA-)PET/CT-imaging).

Exclusion criteria

- Concomitant malignancy (except from BCC of the skin).
- 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.
- Any known allergy for the upfront therapy.
- Any known allergy for LHRH agonist.
- Starting on other upfront combination therapy than abiraterone or

apalutamide.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 16-12-2021

Enrollment: 150

Type: Actual

Medical products/devices used

Generic name: PSMA-PET scan

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 19-10-2021

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 03-12-2021

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 05-08-2022

Application type: Amendment
Review commission: METC NedMec

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
CCMO	NL77093.041.21