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

Published: 29-11-2022
Last updated: 20-06-2024

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	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON51572

Source
ToetsingOnline

Brief title
PET-MaN-enza

Condition

- Miscellaneous and site unspecified neoplasms benign
- 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: Ministerie van OC&W,Astellas Pharma

Intervention

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

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 parameter: Predictive value of baseline PSMA-PET/CT imaging on time to development of CRPC, Predictive value of early response to ADT only on time to development of CRPC, Predictive value of early response to ADT combined with upfront therapy on time to development of CRPC, Analysis of response in different subgroups of patients: e.g. high versus low tumour load, high versus low PSA, high versus low Gleason score, low versus high age

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 on PSMA PET/CT, 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 enzalutamide, including baseline diagnostic PSMA-PET/CT. The timing of follow-up PSMA-PET/CT imaging will be standardized. Instead of imaging at biochemical or clinical signs of disease progression, one PSMA-PET/CT will be performed after two months of hormonal therapy, one PSMA-PET/CT will be performed after two 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 enzalutamide therapy
- Any initial PSA.
- Any Gleason score.
- Any T-stage.
- Any N-stage.
- Stage M1, with multiple / high volume metastasis: more than three (>3) metastatic lesions (any combination of either lymph node metastasis outside of pelvis, bone metastasis, or visceral metastasis), as seen on PSMA-PET/CT-imaging. As these patients are treated with palliative intent.

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 and/or outcome of the study.
- Any known allergy for the upfront therapy.
- Any known allergy for LHRH agonist or antagonist.
- Starting on other hormonal therapy than LHRH agonist or antagonist (max 4 weeks of androgen blockade (e.g. bicalutamide) is allowed to prevent flare

phenomenon with LHRH agonist).
- Starting on other upfront combination therapy than enzalutamide.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2023
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2022
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	15-03-2023
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
ClinicalTrials.gov	NCT05539300
CCMO	NL81959.041.22

Study results

Date completed: 16-05-2024

Summary results
Trial ended prematurely