Detection of aberrant androgen receptor transcripts in circulating tumour cells as a predictor of resistance to AR- directed treatment in patients with castration-resistant prostate cancer.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON42793

Source
ToetsingOnline

Brief title
Detection of AR splice variants in CTC of men with CRPC.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
castration-resistent prostate cancer, progression during hormonal treatment

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Antwerpen
Source(s) of monetary or material Support: IOF onderzoeksfonds Universiteit Antwerpen en de Stichting Tegen Kanker

Intervention

Keyword: Androgen receptor splice variants Predictive Biomarkers Castration-resistant prostate cancer, Circulating tumour cells

Outcome measures

Primary outcome

The determination of the clinical relevance for the presence or absence of

androgen receptor splice variants in circulating tumour cells from patients

with CRPC (with or without previous taxane chemotherapy) is the primary

endpoint of this study.

Secondary outcome

NA

Study description

Background summary

The hypothesis is that in absence of the ligand-binding domain (LBD) of the androgen receptor (AR) in circulating tumour cells (CTC) of patients with castration-resistant prostate cancer (CRPC), new AR-targeted treatment strategies (abiraterone acetate and enzalutamide) would lose their effectiveness and that an a priori resistance would thus exist against these drugs.

Study objective

The objective of this study is to evaluate the clinical validation of a sensitive molecular assay to detect the presence of wild-type (so-called *full-length*) and alternatively spliced variants (ARV) of the AR in enriched CTC of patients with CRPC, with progression of disease, as defined by a confirmed

increase in serum prostate specific antigen (PSA) levels, imaging and/or clinical criteria.

Study design

Via a non-interventional prospective clinical trial we wish to collect extra blood samples on three time points (before treatment initiation, at treatment response and eventually at progression) from patients with castration-resistant prostate cancer (CRPC). In these blood samples the presence or absence of ARV in CTC prior to AR-targeted therapy (i.e. abiraterone acetate or enzalutamide) will be evaluated by targeted RT-qPCR, as a predictor of clinical benefit from these AR-directed therapies.

Study burden and risks

NA

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

1. Willing and able to provide written informed consent
2. Male and age >= 18 years
3. Histologically or cytologically confirmed adenocarcinoma of the prostate
4. Patients eligible to receive enzalutamide or abiraterone acetate as judged by the treating physician
5. Patients with or without prior chemotherapy regimens

Exclusion criteria

1. Serious or uncontrolled co-existent non-malignant disease, including active and uncontrolled infection.
2. Not willing to comply with the procedural requirements (extra blood draw) of this protocol.
3. Any criteria which renders patients ineligible for new AR-directed therapy (i.e. abiraterone acetate, enzalutamide).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	06-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53474.078.15