Castration-resistant prostate cancer registry: An observational study in the Netherlands.
Gevorderd, castratie-resistent prostaatkanker: Een observationele studie in Nederland.

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

Samenvatting

ID

NL-OMON22469

Bron
NTR

Verkorte titel
CAPRI

Aandoening

castration-resistant prostate cancer

Ondersteuning

Primaire sponsor: institute for Medical Technology Assessment (iMTA), Erasmus University, Rotterdam
Overige ondersteuning: CAPRI was funded by Sanofi-Aventis Netherlands B.V., Janssen-Cilag B.V., Astellas Pharma B.V., and Bayer B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate treatment patterns and outcomes in CRPC in daily practice:
1. Response and adverse events of systemic anti-cancer agents in CRPC (including Progression Free Survival (PFS) and Overall Survival (OS));
2. Resource use and costs of systemic anti-cancer agents in CRPC;
3. Patient reported outcomes (including health related quality of life) (in side study).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
The annual incidence of CRPC in the Netherlands is estimated at 2868 patients. Recent developments in anti-cancer agents have proven to be of clinical benefit, at the expense of increased budgetary impact. However, little is known about the clinical effectiveness and cost-effectiveness in daily practice. These insights will contribute to improvement of quality of care in CRPC treatment.

Study Objectives:
To investigate treatment patterns, resource use and outcomes (response, adverse events) of CRPC treatment in daily practice.

Patient population:
3,600 patients, that is approximately 15% of all CRPC patients in the Netherlands, were included. The inclusion period was from 1-1-2010 to 31-12-2015. Data collection ended at 31-12-2017.

Study design:
A retrospective observational, non-controlled, non-randomized registry.

Study centers:
20 hospitals participated, balanced geographically and by type of hospital, with the aim to provide a representative selection of all CRPC patients in the Netherlands.

Methodology:
Data were identified and abstracted from patient records in participating hospitals by trained employees of the institute of Medical Technology Assessment (iMTA). A web-based eCRF was be used for data collection.

Plans for data analysis:
Including, but not limited to: Pre-planned interim analyses; Clinical effectiveness in daily practice (PFS, OS); Serious adverse drug reaction rate; Resource use description; Subgroup analysis (age groups, treatment strategy, geographic regions); Cost-effectiveness analysis (economic decision model).

Doel van het onderzoek

The annual incidence of castration-resistant prostate cander (CRPC) in the Netherlands is estimated at 2868 patients. After development of CRPC, survival with best supportive care is not expected to exceed 12 months. Fortunately, several new treatments (cabazitaxel, abiraterone acetate plus prednisone, enzalutamide and radium-223) for CRPC have been registered. Since the new drugs have different mode of action and can be given in sequence, survival is extended to over 24 months for patients who have access to these treatments. Little is known about treatment patterns (including differences of outcomes between regions and changes in patterns over time), the factors that influence choice of treatment, patient reported outcomes and clinical effectiveness as well as cost effectiveness in daily practice.

Onderzoeksopzet

Every participating hospital was visited for data entry at least annually.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with castration-resistant prostate cancer, as defined by either the treating doctor/physician, or by the definition: prostate cancer that is progressing despite medical or surgical castration (i.e. castrate levels of testosterone (<1,7 nmol/L). If no testosterone has been measured, treatment with surgical castration or medical castration (LHRH-agonists or -antagonists) has to be initiated prior to progression of prostate cancer;
2. Patients diagnosed with CRPC after 01-01-2010 and before 01-01-2016.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Lack of follow up (i.e. a second opinion without treatment (typically 1 or 2 outpatient clinic visits) or a single diagnostic procedure without treatment).

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 gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	3750
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-08-2012
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	NL3440
NTR-old	NTR3591
Ander register	METC VUmc : 2012/272
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
H.M. Westgeest et al 2018. Differences in Trial and Real-world Populations in the Dutch Castration-resistant Prostate Cancer Registry. Eur Urol Focus. 2018 Sep;4(5):694-701. doi: 10.1016/j.euf.2016.09.008. Epub 2016 Oct 13.

H.M. Westgeest et al 2019. Second line cabazitaxel treatment in castration-resistant prostate cancer (CRPC) clinical trials compared to standard of care in CAPRI: an observational study in

the Netherlands.Clinical Genitourinary Cancer(2019), doi:
https://doi.org/10.1016/j.clgc.2019.05.018.