Metastatic hormone-sensitive and castration resistant prostate cancer registry: CAPRI 3.0

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24783

Source
NTR

Brief title
CAPRI 3.0

Health condition

Metastatic hormone-sensitive and castration resistant prostate cancer.

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: Stichting CAPRI

Intervention

Outcome measures

Primary outcome

The main objective is to assess effectiveness, efficiency and quality of treatments in HSPC and CRPC patients in the Netherlands.

Secondary outcome

- To describe the population of HSPC and CRPC patients;
- To assess treatment patterns and outcomes of systemic anti-cancer treatment in HSPC and CRPC;
- Focus on systemic treatment (including hormonal therapy, chemotherapy, bone directed therapy, immunotherapy, targeted therapy), radiotherapy, radionuclides and surgery;
- Focus on relevant and readily available outcomes (including overall survival, treatment duration, biochemical response, severe adverse events);
- To assess guideline adherence of diagnostic evaluation and anti-cancer treatment;
- To assess access of patients to treatment innovations, mainly clinical trials and new treatment options;
- To evaluate differences in real-world populations and trial populations.

Study description

Background summary

Rationale: Annually 2,800 patients die of prostate cancer in the Netherlands. 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 the improvement of quality of care in hormone sensitive prostate cancer (HSPC) and castration resistant prostate cancer (CRPC).

Objective: To investigate the effectiveness, efficiency and quality of care in HSPC and CRPC in daily practice.

Population: Patients will be included after written informed consent in two cohorts: HSPC and CRPC cohort. HSPC-patients can in time progress to the CRPC cohort. The inclusion of the cohorts will start from 01-01-2016 onward.

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

Study centers: Data collection will start in 3-5 hospitals in 2021 which will expand to ≥40 hospitals in 2022.

Methodology: Patients will be identified based on the in- and exclusion criteria using a software tool developed by CTcue B.V. Patients will be asked for informed consent by the treating physicians prior to inclusion. Data will then be abstracted from the electronic medical record by trained data managers using the CTcue software tool. Data include easily accessible and limited data, including a set of baseline characteristics, all systemic treatments given, resource use, treatment outcomes and survival status. The trained employees will revise and complete the automatically abstracted data. Data will be

transferred to a web-based eCRF to allow easy manual completion and provide audit tracking. Data collection is designed to allow easy extension of the dataset for specific additional analysis.

Analysis: Including, but not limited to survival analysis, surrogate outcome analysis (PSA, ALP, time to next treatment), symptomatic skeletal events, serious adverse events (hospitalization and death), resource use and (cost)-effectiveness analysis. Subgroups of interest include patients treated in clinical trials versus real-world patients. Focus on guideline adherence, differential treatment patterns and outcomes in different types of hospitals and regions.

Study objective

Clinical guidelines are based on results of clinical trials and this is not easily generalizable to daily practice due to patient selection. Real-world observations may help to formulate recommendations in guidelines, and yield research questions for new trials. Analyses of real-world data will provide information on:
o Treatment sequencing;
o Patients who are ineligible for trials or underrepresented in trials;
o Characterization of the real-world population and subgroups.

Study design

2021 Start of data collection in 3-5 hospitals. Patients will be retrospectively included with the software of CTcue B.V.. Baseline patient and disease characteristics, conducted treatments including treatments in clinical trials and outcomes will be registered in the web-based database (Castor). Patient identification will be performed two times per year per participating hospital.
2022 Expansion of abovementioned data collection to ≥40 hospitals.
All patients are followed until death, lost-to-follow-up or at least 31-12-2023.
2024 The primary outcomes (effectiveness, efficiency and quality of treatments) will be analysed by comparing treatment characteristics and their costs to overall survival.

Intervention

None.

Contacts

Public
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NA

Scientific
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NA

Eligibility criteria

Inclusion criteria

Patients who were treated in a participating hospital after 01-01-2016 and have:
- metastatic HSPC, defined as involvement of lymph nodes, bones or viscera on radiological assessment or as defined by either the treating doctor/physician (i.e. palliative treatment with surgical or medical castration)
- metastatic CRPC, defined by the treating doctor/physician or the definition of the European Urology Association (EAU)[10], as prostate cancer that is progressing despite medical or surgical castration (i.e. castrate levels of testosterone (≤ 50 ng/dL or <1.7 nmol/L)

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021

Enrollment:	10000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion
Date:	16-03-2021
Application type:	First submission

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
NTR-new	NL9372
Other	CMO Radboudumc : 2020-6573

Study results