Therapeutic strategy in metastatic castration-resistant prostate cancer: target population and changes between 2012 and 2014. Two sequential cohorts within the French nation-wide claims and hospital database (CAMERRA)

First published: 10/04/2018

Last updated: 24/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS21285

Study ID

48948

DARWIN EU® study

No

Study countries

France

Study description

Prostate cancer is the most common cancer in men and represents more than 57,000 new cases each year in France. Several therapeutic options are available at metastatic stage. Since 2004, docetaxel has been the first-line treatment of metastatic castration-resistant prostate cancer (mCRPC). Since 2011, several drugs (cabazitaxel, abiraterone, enzalutamide) successively received European market authorisation as second-line treatment and then as a first-line treatment for the last two. Changes in therapeutic strategies have a major impact on care for mCRPC patients. The research question is to assess the therapeutic strategy changes for mCRPC between 2012 and 2014, as well as the size of the population and healthcare use over three years. Two cohorts of mCRPC patients with a first treatment for mCRPC will be identified from the French nationwide claims and hospital database, and all patients will have a 5-year database history and will be followed during three years. The index date will be the date of the mCRPC first-line treatment initiation during the inclusion period (Cohort 2012: from 1 January 2012 to 31 December 2012, and − Cohort 2014: from 1 January 2014 to 31 December 2014). The main objective is to describe first-line treatment for patients with mCRPC in 2012 and 2014 and then subsequent-line treatments during a 3-year follow-up. Secondary objectives are to estimate the number of patients treated for a mCRPC in 2012 and 2014, to describe characteristics of patients treated for a mCRPC: demographic, comorbidities, and prostate cancer history, to estimate overall survival for all patients and according to the first-line treatment, to describe the complications that could be related to mCRPC treatment, and to describe 3-year healthcare resource use and costs for all patients and according to first-line treatment.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/03/2016

Study start date
Planned: 16/04/2018

Actual: 14/05/2018

Data analysis start date
Actual: 01/10/2018

Date of interim report, if expected
Actual: 31/07/2019

Date of final study report
Planned: 31/12/2019

Actual: 20/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag

Study protocol

CAMERRA_Protocole_vuCEREES v2.1_20180126 vf.pdf (897.5 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe first-line treatment for patients with incident mCRPC in 2012 and 2014 and then subsequent-line treatments during a 3-year follow-up.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Patients with metastatic castration-resistant prostate cancer (mCRPC), aged 40 years or older, initiated docetaxel or abiraterone acetate as the first-line treatment identified from SNDS nation-wide claims and hospital databases between 2012 and 2014.

Inclusion criteria:

• Men of 40 years old and over, alive on the first day of the inclusion period,

• And affiliated to the healthcare insurance system “Régime Général” during the study period,

• And having mCRPC during the inclusion period,

• And initiating a first mCRPC specific treatment during the inclusion period,

• And without any mCRPC specific treatment during the 5-year history before.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Metastatic castrate resistant prostate cancer patients

Estimated number of subjects

10000

Study design details

Outcomes

mCRPC 1st-line therapy. mCRPC is defined as patients with prostate cancer and: -metastatic, based on hospitalisation for metastases, or specific treatment for metastases (e.g. radiofrequency), or metastases specific drug dispensing (e.g. denosumab) -castration-resistant, based on specific drug for prostate cancer (androgen deprivation), CRPC (estramustine), mCRPC (hormonotherapy, cabazitaxel), Overall survival: death at 3-year of follow-up. Complication: hospitalisation with main diagnosis of sepsis, cardiovascular events, adrenal insufficiency, hepatitis fulminant, acute hepatic failure, acute renal failure, rhabdomyolysis, fractures, etc.

Data analysis plan

The following analyses will be performed for each cohort using the total population and according to mCRPC first-line treatment: - Definition of mCRPC stage using preliminary EGB analyses, - A flow chart depicting the number of patients and sequences of treatment available in the database satisfying the cohort criteria and follow-up duration, - Description of baseline characteristics,

comorbidities and prostate cancer history, - Description of first-line treatment for mCRPC patients in 2012 and 2014 and then subsequent-line treatments during a 3-year follow-up, - Estimation of overall survival using time to events methods, - Description of complications that could be related to mCRPC treatment, - Description of the 3-year healthcare resources use and costs.

Documents

Study results

CAMERRA Poster_2020_ASCO_v1.0 final-edited on 20201021.pdf (2.74 MB)

Study publications

Thurin NH, Rouyer M, Gross-Goupil M, Rebillard X, Soulié M, Haaser T, Roumiguié…

Thurin NH, Rouyer M, Jové J, Gross-Goupil M, Haaser T, Rébillard X, Soulié M, d…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Annex5_DoIForm-PBl.pdf (224.94 KB)

Composition of steering group and observers

Composition steering committees CAMERRA.pdf (70.38 KB)

Signed code of conduct

Annex3_Declaration-CAMERRA signed.pdf (54.37 KB)

Signed code of conduct checklist

Annex2_Checklist-CAMERRA signed.pdf (466.64 KB)

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols-CAMERRA_20180307.docx.pdf (342.08 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No