Second primary cancers in patients with castration resistant prostate cancer (BOCARP)

First published: 04/03/2016

Last updated: 13/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12665

Study ID

26612

DARWIN EU® study

No

Study countries

Germany

Study description

This study aims at estimating the incidence of second primary malignancies as well as the overall survival among metastasized prostate cancer (mPC) and metastasized castrate-resistant prostate cancer (mCRPC) patients not treated with radium-223-dichloride.

Study status

Finalised

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 30/03/2026

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Riedel Oliver

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/07/2015

Actual: 10/07/2015

Study start date
Planned: 15/03/2016

Actual: 15/03/2016

Date of final study report
Planned: 30/11/2017

Actual: 20/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

Study 18044_Protocol_2016-03-03_final.pdf (607.63 KB)

18044_study protocol_v1.2_2017-05-02.pdf (1.15 MB)

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

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Background Incidence Study

Data collection methods:

Secondary use of data

Main study objective:

Incidence of second primary malignancies in patients with castration resistent prostate cancer.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Prostate cancer metastatic

Population studied

Short description of the study population

Prostate cancer patients with bone metastases (mPC) and among a subgroup of Mpc patients among whom the prostate cancer was castration-resistant (mCRPC).

Patients with valid information on sex, age and the region of residence, a period of at least 12 months of continuous insurance preceding cohort entry, diagnosis of PC (ICD-10 Code C61) in the study period (January 1, 2004 – December 31, 2011), diagnosis of bone metastases (ICD-10 Code C79.5) in the enrolment

period (January 1, 2005 – December 31, 2011) were included in the mPC cohort. Members of the mCRPC cohort should have one of the following in the enrolment period and before or at the same time with bone metastases
a. Discontinuation of the initial chemical castration, change of the agent or modality of the ADT, or start of treatment for advanced PC after the primary ADT
b. Surgical castration and initiation of ADT treatment
c. Treatment with medication specific to mCRPC or hormone-refractory PC. These are cabazitaxel, enzalutamide, abiraterone, estramustine, docetaxel, mitoxantrone, as well as sipuleucel-T, which are indicated for advanced hormone-refractory PC in Germany

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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

Prostate cancer metastatic patients

Estimated number of subjects

2.100

Study design details

Outcomes

Incidences of Second primary malignancies are characterized by the following ICD-10 codes: C00-C76, C81-C96, D00-D09, D37-D48. - Up to 10 years, Overall survival - Up to 10 years

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Data analysis plan

The incidence of second primary malignancies will be calculated. Overall survival will be described. Details on analysis will be described in the Statistical Analysis Plan (SAP).

Documents

Study results

18044_EU-PAS_Abstract_2018-11-12.pdf (69.18 KB)

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.

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

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

Unknown