Incidence of Second Primary Malignancies in Patients With Castration-Resistant Prostate Cancer: An Observational Retrospective Cohort Study in the US

First published: 27/05/2016

Last updated: 20/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13602

Study ID

32030

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study is conducted to estimate population-based incidence rates of second primary malignancies among patients with CRPC similar to those treated with Xofigo. These rates will provide context for second primary malignancy incidence rates from the REASSURE study.Furthermore this study aims to provide further information about the documentation of bone metastases in Medicare data and the extent of use of only oral androgen deprivation drugs among patients with Medicare Part D coverage, as well as to estimate overall survival of the study population.Xofigo (radium-223 dichloride) is an alpha-emitting pharmaceutical, which was approved for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases, and no known visceral metastatic disease. The long-term safety profile of Xofigo is evaluated in the prospective REASSURE study, which estimates the incidence rates of second primary malignancies in patients with CRPC receiving Xofigo. To provide context on that, this retrospective study is conducted to estimate background rates of second primary malignancies among patients with CRPC similar to those who are treated with Xofigo.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

James Kaye

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 04/11/2015

Study start date

Planned: 15/06/2016

Actual: 20/05/2016

Date of final study report
Planned: 28/07/2017

Actual: 05/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

18673_Study Protocol_V1.0_2016-03-09_Redacted.pdf(569.93 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:

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

Population studied

Short description of the study population

Men aged 65 and older in the US enrolled in Medicare with castrate resistant prostate cancer identified after January 1, 2006.

The study cohort included men who meet all of the following inclusion criteria:
• Enrolled in both Medicare Parts A and B for at least 1 year before the cohort entry date (minimum lookback period for comorbidities and treatments)
• Primary site code of prostate cancer (International Classification of Diseases for Oncology, Third Edition [ICD-O-3] 1 topography code C61.9) in SEER data
• Surgical castration or androgen deprivation therapy after prostate cancer diagnosis; androgen deprivation therapy will be indicated by the use of any of the following drugs: abarelix, bicalutamide, buserelin, cyproterone, degarelix, diethylstilbestrol, estramustine, flutamide, gonadorelin, goserelin, histrelin, leuprolide,
medroxyprogesterone, megestrol, nafarelin, nilutamide, polyestradiol, triptorelin
• Evidence that prostate cancer was resistant to surgical castration or androgen deprivation therapy (“castration-resistant prostate cancer”), as indicated by starting one of the following second-line systemic therapies (cohort entry date): abiraterone, cabazitaxel, docetaxel, enzalutamide, mitoxantrone, or sipuleucel-T
• Cohort entry date 01 January 2006 or later
• Age 65 years or older on the cohort entry date

Age groups

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 patients

Estimated number of subjects

15750

Study design details

Outcomes

Estimation of the collective incidence rate of all second primary malignancies (other than nonmelanoma skin cancer) among men with CRPC (Castration-Resistant Prostate Cancer) &Estimation of the individual incidence rates of selected second primary malignancies, Estimation of the proportion of men with CRPC who have a diagnostic code for bone metastases in their Medicare claims before development of CRPCEstimation of the proportion of men with CRPC who received bone-directed therapies before development of CRPCEstimation of the proportion of men with CRPC + Medicare Part D coverage who received only oral androgen deprivation therapyOverall survival

Data analysis plan

Characteristics of study subjects will be described. The incidence of second primary malignancies will be calculated. Overall survival will be described.

Documents

Study results

18673_EUPAS Abstract_2019-04-30.pdf(552.82 KB)

Study report

18673_Clinical Study Report_Combined_2018-05-09_Redacted.pdf(1.09 MB)

Study publications

Saltus CW, Vassilev ZP, Zong J, Calingaert B, Andrews EB, Soriano-Gabarró M, Ka...

Kawai AT, Martinez D, Saltus CW, Vassilev ZP, Soriano-Gabarró M, Kaye JA. Incid...

Kaye JA, Saltus CW, Calingaert B, Harris DH, Hunter S, Zong J, Brobert GP, Sori...

Saltus C, Harris D, Calingaert B, Andrews EB, Zong J, ..., Kaye JA, et al. Identi...

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 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