Incidence of Second primary Malignancies in prostate Cancer patients with bone metastases – an observational retrospective cohort study in Sweden (SMARCOS)

First published: 10/11/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS15491

Study ID

26899

DARWIN EU® study

No

Study countries

Sweden

Study description

An observational retrospective cohort study in Sweden to investigate incidence of second primary malignancies in prostate cancer patients with bone metastases

Study status

Finalised

Research institutions and networks

Institutions

EPID Research Oy

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Institution

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

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Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2015

Actual: 20/11/2015

Study start date
Planned: 15/11/2016

Actual: 15/11/2016

Date of final study report
Planned: 06/10/2017

Actual: 06/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer HealthCare Pharmaceutical Inc

Study protocol

ER-9508_mCRPC_Study_Protocol (18105) 20160120 FINAL.pdf (652.92 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:

To evaluate the incidence of developing any second primary malignancy among prostate cancer patients with bone metastases (mPC) and among a subgroup of mPC patients whom the prostate cancer is castration-resistant (mCRPC).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Second primary malignancy

Population studied

Short description of the study population

Patients with prostate cancer having diagnosis in 1.1.1998 – 31.12.2013 and with bone metastases diagnosis or bone-directed treatments in 1.1.1998 – 31.12.2013 will be initially included into the large study population.

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 patients

Estimated number of subjects

15.000

Study design details

Outcomes

incidences of Second primary malignancies that are characterized by the following ICD-10 codes: C00-C76, C81-C96, D00-D09, D37-D48. 1.Incidences of any site-specific second primary malignancies2.Overall survival3.Pathologic fracture4.Spinal cord compression5.Surgery to bone6.Radiation to bone

Data analysis plan

Characteristics of study subjects at cohort entry will be described. The incidence rate (and its 95% Confidence Interval) of any second primary malignancies will be calculated as a ratio of the number of incident cases and total follow-up time. Overall survival will be studied as time from cohort entry to death due to any cause. The survival time will be described with summary statistics. Yearly survival rates and Kaplan-Meier survival curves will be reported. Details on analysis will be described in the Statistical Analysis Plan (SAP).

Documents

Study results

18105_EU-PAS_Abstract.pdf (62.18 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 sources (types)

Disease registry

Drug registry

Other

Data sources (types), other

Swedish Population Register, The Cause of Death Register, The National Patient Register (NPR)

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