PRECISE/Rates of bone fractures and survival in metastatic castration-resistant PRostate cancer (mCRPC) PatiEnts treated with Radium-223 in routine Clinical practIce in SwedEn

First published: 05/02/2020

Last updated: 20/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS33448

Study ID

42249

DARWIN EU® study

No

Study countries

Sweden

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

Networks

The Prostate Cancer data Base Sweden (PCBaSe)

Contact details

Study institution contact

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

Study contact

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Primary lead investigator

Pär Stattin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/12/2018

Actual: 05/12/2018

Study start date

Planned: 15/02/2020

Actual: 15/02/2020

Date of final study report

Planned: 30/06/2021

Actual: 14/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

20437_Study Protocol_V2.1_2019-09-06_Redacted.pdf (2.1 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/PSP/S/0076

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective in this study is to estimate the effect of Ra-223 on the incidence of bone fractures compared with other standard treatments for mCRPC.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XOFIGO

Medical condition to be studied

Prostate cancer metastatic

Population studied

Short description of the study population

Population comprises men with mCRPC in the PCBaSe data set during the study time frame. No sampling will be performed.

The selection criteria have been chosen to select a population as similar as possible to the one

included in the ALSYMPCA and ERA 223 trials.

• Inclusion criteria (all of the following must be present):

• Histologically confirmed adenocarcinoma of the prostate, i.e., the patient is registered in the NPCR (histology other than adenocarcinomas are not registered in the NPCR).

• Start of any systemic treatment for mCRPC as an nth line of treatment, where n goes from 1 to 4. The following will be considered systemic treatment for mCRPC: Ra-223, docetaxel, cabazitaxel, enzalutamide, abiraterone, and the following group of less commonly used drugs in Sweden, which will be labelled as “others”—cisplatin, cyclophosphamide, doxorubicin, estramustine, etoposide, gemcitabine, carboplatin, methotrexate, mitoxantrone.

• Prostate cancer progression to ADT or subsequent lines of therapy. Prostate cancer progression will be surrogated by the initiation of a drug specific for mCRPC in the first or later lines of treatment.

• Eastern Cooperative Oncology Group performance status of 0-2 at treatment initiation.

We will assume that patients starting any of the systemic therapies under study have a performance status of 0-2.

• Presence of bone metastasis. We will assume that all patients receiving Ra-223 have bone metastasis and will select for the comparator group those with recorded bone metastasis.

• Exclusion criterion (includes either of the following):

• Prior use of Ra-223

• Patients that have participated in a Ra-223 RCT

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

3800

Study design details

Outcomes

1. Bone fractures requiring admission to a hospital or treated in an outpatient setting, as recorded or captured in the PCBaSe , 1. Death due to all causes 2. Death due to prostate cancer

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Data analysis plan

The primary outcome will be the incidence of bone fractures. The numerator will be the number of symptomatic bone fractures identified during Ra-223 use, and the denominator will be the sum of all person-years of follow-up for

symptomatic bone fractures. The secondary outcomes are death due to all causes and death due to prostate cancer. The cumulative incidence of bone fractures, all-cause mortality, and prostate cancer–specific mortality will be estimated using the Kaplan-Meier estimator, and 95% confidence intervals will be computed using Greenwood’s formula.

Documents

Study results

20437_EU PAS Abstract_Redacted_V1.0_2021-06-14.pdf (106.97 KB)

Study report

20437_Study Report_Redacted_V1.0_2021-06-14.pdf (3.51 MB)

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

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