URANIS –Data collection in urological centers during treatment with Ra-223 dichloride (Xofigo) within the framework of a non-interventional study assessing overall survival (OS) and effectiveness predictors of Ra-223 dichloride treated mCRPC patients in a real life setting in Germany

First published: 01/08/2018

Last updated: 11/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24796

Study ID

43099

DARWIN EU® study

No

Study countries

Germany

Study description

This observational prospective single arm cohort study is designed to examine overall survival, symptomatic skeletal event free survival and quality of life of metastatic Castration Resistant Prostate Cancer (mCRPC) patients receiving Radium-223 under real life conditions. In addition, time to next tumor treatment (TTNT), mobility, quality of life and self-care (Moses-Questionnaire), independence in activities of daily living and safety will be examined.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/03/2015

Study start date

Planned: 31/05/2015

Actual: 28/05/2015

Date of final study report

Actual: 01/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

18043_URANIS_CSP_V4.0_2018-04-30.pdf(1.06 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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

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

Overall survival

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is to evaluate the overall survival during Radium-223 dichloride treatment of mCRPC patients in a real life setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XOFIGO

Study drug International non-proprietary name (INN) or common name

RADIUM RA 223 DICHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(V10XX03) radium (223Ra) dichloride

radium (223Ra) dichloride

Medical condition to be studied

Prostate cancer metastatic

Population studied

Short description of the study population

Male patients with a diagnosis of mCRPC with symptomatic bone metastases without known visceral metastases will be enrolled after the decision for treatment with Radium-223-dichloride has been made by the attending physician according to his/her medical practice.

Inclusion criterion/criteria

- Male patients diagnosed with castration resistant adenocarcinoma of the prostate (CRPC) with symptomatic bone metastases without known visceral metastases
- Decision to initiate treatment with Radium-223 was made as per investigator’s routine treatment practice.
- Signed informed consent

Exclusion criterion/criteria

- Patients participating in an investigational program with interventions outside of routine clinical practice and also in all non-interventional studies focusing on Radium-223-dichloride.

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

77

Study design details

Outcomes

Overall survival, Explore symptomatic skeletal event free survival.Examine the incidence of treatment-emergent adverse events.Calculate the incidence of pathological fractures,non-pathological fractures and bone associated events.Explore treatments and time to subsequent mCRPC treatment.Examine the QoL as patient reported outcome using FACT-P.Explore independence in activities of daily livingby using the Katz-index

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Data analysis plan

Statistical analyses will be primarily of explorative and descriptive nature. All analyses will be provided for the complete study population, as well as separately for the chemotherapy naïve vs non naïve study population. Patients receiving at least one dose of Radium-223 will be considered valid for safety analysis set. Time to event variables (OS, SSE-FS, TTNT) will be summarized using Kaplan-Meier estimates. Median event times together with the 25th and 75th percentiles and associated 95% confidence intervals will be presented. Analyses of QoL will be performed for patients with evaluable patient questionnaires (FACT-P) at each visit. Descriptive statistics (e.g. means, mean changes) will be provided for each assessment time point. The study analyses will be descriptive and no formal hypothesis testing will be performed.

Documents

Study results

18043_EU PAS Abstract_Redacted_V1.0_2021-09-01.pdf(281.83 KB)

Study, other information

18043_URANIS_OSR_Redacted_final v.1.0_2021-09-01.pdf(1.22 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective patient-based data collection

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