PARABO - Pain evaluation in Radium-223 (Xofigo®) treated mCRPC patients with bone metastases – a non-interventional study in nuclear medicine centers

First published: 20/03/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42732

EU PAS number

EUPAS9020

Study ID

42732

DARWIN EU® study

No

Study countries

Germany

Study description

This observational prospective single arm cohort study is designed to assess pain and bone pain related quality of life of metastatic Castration Resistant Prostate Cancer (mCRPC) patients receiving Radium-223 in a real life nuclear medicine practice setting. In addition, overall survival, time to next tumor treatment (TTNT), time to first symptomatic skeletal event (SSE), course of blood counts, and safety will be assessed.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

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Institution

Multiple centres: 30 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/09/2014

Actual: 05/09/2014

Study start date

Planned: 31/03/2015

Actual: 19/03/2015

Date of final study report

Planned: 29/01/2021

Actual: 01/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

XF1412_CSP_v1.0_2014-09-12_signed_reduced.pdf(766.62 KB)

17550_PARABO_CSP_v6.0_2018-04-30_redacted.pdf(2.37 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:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is to evaluate pain response during Radium-223 treatment of mCRPC patients in a real life nuclear medicine practice setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

Inclusion criterion/criteria

- Male patients diagnosed with 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

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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 patients

Estimated number of subjects

350

Study design details

Outcomes

Pain response, Change of pain over time Change in bone pain related quality of life Pain control rate Pain progression rate Time to first pain progression Time to first opioid use Summary evaluation of covariates on pain response Relation between bone uptake in known lesions and pain palliation Dosage of Radium-223 Number of injections of Radium-223 Overall survival + 10 other secondary outcomes

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Data analysis plan

Statistical analyses will be primarily of explorative and descriptive nature. Patients receiving at least one dose of Radium-223 will be considered valid for safety analysis set. Analyses of pain or QoL will be performed for patients with evaluable patient questionnaires (BPI-SF, FACT-BP, respectively) at baseline and at least one post baseline visit. A clinically increase or decrease in opioid use will be taken into account. Further details will be defined in the SAP. Other analyses will be performed for the safety analysis set unless otherwise defined. Whenever reasonable, data will be stratified by subgroups (i.e. age, other baseline characteristics). All therapies documented will be coded using the World Health Organization – Drug Dictionary (WHO-DD). Medical history, any diseases and AEs will be coded using the latest MedicalDictionary for Regulatory Activities (MedDRA) version. It is planned to have one interim analysis at the time of 6 months after LPFV.

Documents

Study results

17750_EU PAS Abstract_2021-07-07.pdf(332.87 KB)

Study report

17550_Clinical Study Report_V1.0_20210601_redacted.pdf(9.86 MB)

17550_Clinical Study Report_V2.0_2021-06-28_redacted.pdf(1.46 MB)

Study, other information

17550_Clinical Study Report_V2.0_2021-06-28_redacted.pdf(1.46 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Medical records

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