Prospective observational study to describe routine use of XGEVAâ for prevention of skeletal related events (SREs) in subjects with bone metastases from prostate carcinoma in Bulgaria (20180095)

First published: 19/12/2018

Last updated: 17/04/2023

Study Finalised

Administrative details

EU PAS number

EUPAS26983

Study ID

48138

DARWIN EU® study

No

Study countries

☐ Bulgaria

Study description

The study will address the question of the use of XGEVAâ for prevention of SREs in subjects with bone metastases from prostate carcinoma in Bulgaria. The primary objective is to describe real life patterns of bone metastases management and routine use of XGEVA® for SREs prevention in subjects with bone metastases from hormone sensitive and castration-resistant prostate carcinoma. The secondary objectives are to estimate the incidence of SREs, healthcare utilization and pain management.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 10 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/04/2018

Actual: 12/04/2018

Study start date

Planned: 31/05/2019

Actual: 17/05/2019

Data analysis start date

Planned: 29/01/2021

Actual: 31/03/2021

Date of final study report

Planned: 31/08/2022

Actual: 16/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180095_01.02.06 Public Redacted Protocol Ver 1.0 2018-10-24 English.pdf
(255.48 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Routine use of XGEVA® for prevention of skeletal related events (SREs) in subjects with bone metastases from prostate carcinoma

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to describe real life patterns of bone metastases management and routine use of XGEVA® for SREs prevention in subjects with bone metastases from prostate carcinoma.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre, prospective, observational study

Study drug and medical condition

Medicinal product name

XGEVA

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Adult patients aged 18 years or older diagnosed with bone metastases from hormone-sensitive prostate carcinoma (HSPC) and castrate-resistant prostate carcinoma (CRPC) received treatment with XGEVA® in routine clinical practice between January 2019 to January 2021 in Bulgaria.

Inclusion Criteria:

I. Patient at least 18 years old at the time of ICF signature

II. Patient with histologically or cytologically confirmed diagnosis of prostate carcinoma with at least one bone metastasis lesion confirmed by imaging (X-ray, MRI, or CT)

III. Patient received between one and three XGEVA® administrations in the timeframe of six months prior to enrolment

IV. Patient provided written informed consent

Exclusion Criteria:

I. Patient with bone metastases previously treated in the last six months with bisphosphonates or other bone-targeting agents (BTAs) for prevention of SREs in clinical trial or routinely

II. Patient with prostate carcinoma as a second primary malignancy

III. Patient with brain metastases

IV. Patient currently enrolled in trial with investigational drug for treatment/prevention of bone metastases and SREs

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

Patients with bone metastases

Estimated number of subjects

100

Study design details

Outcomes

Demographic and clinical characteristics of subjects with bone metastases from HSPC and CRPC receiving XGEVA® in clinical routine practice. Treatment patterns. Estimate the incidence of SREs and symptomatic SREs (SSEs) in patients with bone metastases from hormone sensitive and CRPC. Describe patient and/or physician reported factors that influence adherence to treatment based on data obtained via specific questionnaires, namely: Beliefs about medicines questionnaire (BMQ)

Data analysis plan

The analysis of this study will be descriptive in nature. Counts and percentages will be provided for categorical outcomes. Continuous outcomes will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values. Cumulative incidence for SREs will be analysed with Andersen-Gill method for recurrent events, treating death as competing risk. For each outcome parameter, the impact of covariates will be assessed using generalized linear models, when appropriate. The detailed description of covariates and subgroups analysis will be enclosed to the Statistical Analysis Plan (SAP). If available, non-significant factors will be eliminated stepwise until only covariates significant at the 5% level remain, thereby indicating which covariates have an important influence on treatment pattern. The final decision about removing or keeping the variable from the analysis will be taken based on the medical knowledge of spon

Documents

Study results

20180095 01.47.01.01 Observational Research Study Report Published Report_Redacted.pdf (492.48 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)

Other

Data sources (types), other

Phycisian’s 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