Incidence of new Primary Malignancies Among Patients With Bone Metastases From Breast, Prostate, or Lung Cancer Treated With XGEVA or Intravenous Zoledronic Acid: a Retrospective Cohort Study (20170728)

First published: 26/09/2018

Last updated: 28/02/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33874

EU PAS number

EUPAS25381

Study ID

33874

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study is to estimate the incidence of any new primary malignancy (any haematologic or non-haematologic tumour, excluding non-melanoma skin cancer subsequent to the first primary malignancy) among patients with breast, prostate, or lung cancer and bone metastases following initiation of either XGEVA or zoledronic acid, and to describe the types of new primary malignancies that patients experience, as well as the characteristics of the patients who develop new primary malignancies. The study employs a retrospective cohort design and data from the SEER-Medicare linked datasets.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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: 13/03/2018

Actual: 13/03/2018

Study start date

Planned: 14/12/2018

Actual: 11/12/2018

Data analysis start date

Planned: 01/03/2019

Actual: 01/03/2019

Date of final study report

Planned: 01/03/2020

Actual: 28/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen, Inc.

Study protocol

20170728_01.02.06 Public Redacted Protocol Ver 1.0 English.pdf(703.48 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To estimate, overall and by primary malignancy site, incidence (rate, cumulative incidence proportion) of any subsequent new primary malignancy (any haematologic or non-haematologic tumours, excluding non-melanoma skin cancer after the first primary malignancy) among patients with breast, prostate, or lung cancer and bone metastases who were newly treated with either XGEVA or IV zoledronic acid

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XGEVA

Medical condition to be studied

Breast cancer stage IV

Prostate cancer stage IV

Non-small cell lung cancer stage IV

Population studied

Short description of the study population

Patients aged 18 years or older who were diagnosed with a first primary, microscopically confirmed breast, prostate, or lung cancer in SEER between 2000 and 2014. Patients must have received their first record for XGEVA or ZA between 2011 and 2014, and had a record of bone metastases within 30 days before or after this date in the Medicare claims data (ICD-9-CM code 198.5 or ICD-10-CM code C79.5) or had a record of bone metastases in the SEER data at diagnosis.

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

Breast, prostate, or lung cancer patients

Estimated number of subjects

15000

Study design details

Outcomes

New primary malignancy (any haematologic or non-haematologic tumours, excluding non-melanoma skin cancer subsequent to the first primary malignancy)

Data analysis plan

This is a descriptive study and will focus on exposure cohort-specific analyses (XGEVA, intravenous zoledronic acid). No formal statistical comparisons or significance testing are planned. The primary analyses estimate the incidence rate and cumulative incidence proportion of new primary malignancy in each exposure cohort using 95% confidence interval as a measure of the uncertainty of the estimates. Cumulative incidence proportions will account for the competing risk of death. Analyses will be conducted both for index malignancy types combined and individually (breast, prostate, lung).

Documents

Study results

01.09.01 Clinical Study Report ORSR Abstract 2020-01-29 20170728 Final Analysis.pdf(85.58 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Other

Data sources (types), other

Disease registry data linked with administrative claims

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