The use and safety of XGEVA or Zoledronic acid in clinical practice among Chinese patients with bone metastases from breast, lung, or prostate cancer – a retrospective cohort study within Taiwan’s Health Insurance Research Database (20190412)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46008

EU PAS number

EUPAS39611

Study ID

46008

DARWIN EU® study

No

Study countries

Taiwan

Study description

This study is a retrospective cohort study aiming to describe the utilization of XGEVA and Zoledronic acid and to characterize the safety of XGEVA among Chinese patients with breast, lung, or prostate cancer following diagnosis of incident bone metastases (BMs). The study population will include patients in Taiwan's National Health Insurance (NHI) Database who were diagnosed with bone metastasis secondary to breast, lung or prostate cancer and were newly treated with XGEVA or Zoledronic acid.

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

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/03/2021

Actual: 25/02/2021

Study start date

Planned: 31/05/2021

Actual: 06/04/2021

Data analysis start date

Planned: 17/01/2022

Actual: 17/01/2022

Date of final study report

Planned: 17/01/2023

Actual: 24/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS39611-40005.pdf(842.35 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the use of XGEVA and Zoledronic acid in Chinese patients with breast, lung or prostate cancer following diagnosis of incident bone metastases. The study also will characterize safety of XGEVA as measured by the incidence of osteonecrosis of the jaw (ONJ), atypical femur fracture (AFF), and hypocalcemia.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Name of medicine

XGEVA

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

ZOLEDRONIC ACID

Medical condition to be studied

Lung cancer metastatic

Prostate cancer metastatic

Breast cancer metastatic

Metastases to bone

Population studied

Short description of the study population

The study population included patients 18 years or older diagnosed with bone metastasis (BM) secondary to breast, prostate, or lung cancer received treatment with XGEVA or Zoledronic acid between January 1, 2013 and December 31, 2017 identified from the Taiwan's National Health Insurance Research Database (NHIRD).

Inclusion criteria:

• Diagnosis of BM secondary to breast, prostate, or lung cancer and prior to initial use of XGEVA or Zoledronic acid.

• New user of XGEVA or Zoledronic acid during study period (January 1, 2013 to December 21, 2016)

o New user of either therapy will be defined as not having been treated with any bone targeting agent therapy prior to treatment initiation with XGEVA or Zoledronic acid.

• At least one year of data available prior to initial administration of XGEVA or

Zoledronic acid.

• 18 or older at diagnosis of BM.

Exclusion criteria:

• Patients with diagnosis of giant cell tumor of the bone, or multiple myeloma (to ensure that included subjects are receiving XGEVA for the indication of the treatment of BM from solid tumors).

• Evidence of XGEVA or Zoledronic acid use prior to BM 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

Patients with bone metastasis

Estimated number of subjects

6000

Study design details

Outcomes

Mean number XGEVA or Zoledronic acid prescriptions per patient Treatment duration from first dose to last dose of XGEVA or Zoledronic acid Proportion of patients discontinuing XGEVA or Zoledronic acid for more than 90 days Proportion of patients who switch therapies Time from initial therapy to the switching of therapy Incidences of ONJ, AFF, and hypocalcemia per 100 person years

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Data analysis plan

Primary objective #1 (use of XGEVA or Zoledronic acid) is descriptive and formal hypothesis testing will not be implemented. Primary objective #2 (safety of XGEVA) will estimate the incidence rates of three important identified risk factors in the Global Risk Management Plan for XGEVA, including ONJ, AFF, and hypocalcemia.

Documents

Study results

20190412 Observational Research Study Report Published Report_Redacted.pdf (681.65 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., 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