Integrated Retrospective Analysis of Metastatic-related and Non metastatic-related Fractures in Studies 20050136, 20050244, and 20050103

First published: 16/11/2018

Last updated: 27/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24775

Study ID

30045

DARWIN EU® study

No

Study countries

United States

Study description

Descriptive analysis of on-study metastatic and non-metastatic fractures from studies 20050136, 20050103,and 20050244 in subjects with bone metastases from solid tumors. To describe additional risk factors associated with on-study non-metastatic fractures for subjects with on-study non-metastatic fracture(s) This study will fulfil a postmarketing commitment to the US Food and Drug Administration (FDA) (part of the approval of XGEVA® prior approval supplement which added Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation to Warnings & Precautions section of XGEVA US Prescribing Information).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

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: 19/06/2018

Actual: 19/06/2018

Study start date
Planned: 01/12/2018

Actual: 07/09/2018

Data analysis start date
Planned: 01/03/2019

Actual: 21/11/2018

Date of final study report
Planned: 01/06/2019

Actual: 08/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 2018-06-19 English.pdf (889.99 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

20180024

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To characterize the on-study metastatic and non-metastatic fractures seen in studies 20050136, 20050244 and 20050103

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective analysis

Study drug and medical condition

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

DENOSUMAB

Medical condition to be studied

Bone cancer metastatic

Population studied

Short description of the study population

Subjects with bone metastases from solid tumors.

All subjects randomized on Studies 20050136, 20050103, and 20050244 (excluding 179 subjects with multiple myeloma) will be included in the analysis.

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

Solid tumors patients with bone metastases

Estimated number of subjects

5.723

Study design details

Outcomes

The primary objective is to characterize the on-study metastatic and non-metastatic fractures seen in the 20050136, 20050244 and 20050103 studies. Location of non metastatic fracture (vertebral vs non-vertebral) and fracture CTCAE grades will be assessed. The secondary objective is to describe baseline medications known to reduce bone mineral density (BMD) and/or a history of osteoporosis in those patients experiencing a non-metastatic fracture.

Data analysis plan

The statistical analysis in this study will be descriptive in nature. Categorical outcomes will be summarized by the number and percentage of subjects or events in each category. Continuous outcomes will be summarized by the number of nonmissing values, mean, standard deviation, median, lower and upper quartiles, minimum, and maximum.

Documents

Study results

20180024_01.47.01.01 Observational Research Study Report Published Report_Redacted (002).pdf (159 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

Clinical trial results

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