Prolia® Postmarketing Active Safety Surveillance Program for Soliciting Adverse Events of Special Interest in the United States (PASP-EMR Program)

First published: 16/01/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48699

EU PAS number

EUPAS17198

Study ID

48699

DARWIN EU® study

No

Study countries

United States

Study description

To monitor the long-term safety of Prolia® (denosumab) and enhance the quality of data collection by proactively soliciting adverse event (AE) reporting of the 5 pre-specified AEs of special interest (AESI) from United States (US) health care providers (HCP e.g., physicians, licensed registered nurses, nurse practitioners, or physician assistants) of Prolia treated postmenopausal women and men with osteoporosis within the Postmarketing Active Safety Surveillance Program (PASP) Electronic Medical Record (EMR) (PASP-EMR program).

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

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Study contact

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Primary lead investigator

Akeem Yusuf

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/05/2016

Study start date

Actual: 27/05/2010

Data analysis start date

Planned: 01/03/2022

Actual: 01/03/2022

Date of final study report

Planned: 02/08/2022

Actual: 23/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20090601Protocol Amend 2 2016 Fully Redacted.pdf(555.62 KB)

20090601Protocol Amend 2 2016-06-23.pdf(2.84 MB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To monitor the long-term safety of Prolia® (denosumab) and enhance the quality of data collection by proactively soliciting adverse event (AE) reporting of the 5 pre-specified AEs of special interest (AESI) from United States (US) health care providers (HCP e.g. licensed registered nurses, nurse practitioners, or physician assistants) of Prolia treated postmenopausal women and men with osteoporos

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Postmarketing Active Safety Surveillance Program

Study drug and medical condition

Name of medicine

PROLIA

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

Men and postmenopausal women with osteoporosis receiving Prolia for the treatment identified from the Postmarketing Active Safety Surveillance Program (PASP) Electronic Medical Record (EMR) (PASP-EMR program).

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

Osteoporosis patients

Estimated number of subjects

5000

Study design details

Data analysis plan

Descriptive statistics will be used to summarize the program data. Summary data to be estimated and reported include number of Prolia-treated patients in the electronic medical record(EMR) platform, number and percentage of Prolia-treated with at least 1 AESI-soliciting questionnaire presented and completed, number and perecentage of Prolia-treated patients with at least 1 AESI reported through the EMR platform, number of AESIs reported through a secure Amgen website via a link from the EMR platform and incidence rates for AESIs. Data will be computed and reported annually.

Documents

Study results

denosumab 20090601 Observational Final Analysis Abstract.pdf(216.32 KB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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