Postmarketing Surveillance Study of Prolia (Denosumab) in South Korea

First published: 16/03/2017

Last updated: 22/01/2021

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39173

EU PAS number

EUPAS17915

Study ID

39173

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

To estimate the incidence rates of adverse events and change in bone mineral density in patients being treated with Prolia® in a postmarketing setting as required by the Ministry of Food and Drug Safety

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 40 centres are involved in the study

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: 29/08/2016

Actual: 29/08/2016

Study start date

Planned: 13/10/2017

Actual: 09/05/2017

Data analysis start date

Planned: 29/09/2019

Actual: 18/05/2020

Date of final study report

Planned: 23/12/2020

Actual: 18/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01 20 01 Protocol Ver 1 0 2016-08-29 redacted.pdf(437.96 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

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

Efficacy of a product with marketing authorization

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to estimate the incidence rates of adverse events, serious adverse events, and adverse drug reactions among patients receiving Prolia® in a postmarketing setting as required by the MFDS.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A prospective, observational, multicenter, post-marketing surveillance study

Study drug and medical condition

Name of medicine

PROLIA

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

The study population comprises patients treated with Prolia in a clinical setting which includes any primary through tertiary healthcare setting where Prolia is prescribed.

Patients will be screened for eligibility, receive a single dose of Prolia during their initial visit/day 1 (which could be the same day as screening), and return for follow-up visits at the discretion of the investigator based on the patient’s course of treatment.

Inclusion Criteria

• Patients who receive Prolia (on-label) in the postmarketing setting in South Korea.

• Willing to provide access to previous and future medical information.

• Patients who consent to participate in this study.

Exclusion Criteria

• Patients unwilling to provide consent.

• Patients with hypocalcemia.

• Patients who are pregnant.

• Patients with known hypersensitivity to denosumab or any of its components.

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

3000

Study design details

Outcomes

Incidence of adverse events and adverse drug reactions (including seriousness and causality to drug), inclusive of reaction at local injection sites, will be collected as they become available throughout the follow-up period and reported. Subject level incidence will be reported and summarized by classification according to the adverse event coding, (1) Percent change from baseline in BMD at 12 months (measured by DXA scan) of the lumbar spine, total hip, and femoral neck. (2) Describe characteristics of patients receiving Prolia® in the postmarketing setting

Data analysis plan

Descriptive analysis of the collected safety and efficacy endpoints will be conducted at interim analyses (every 6 months for the first 2 years from approval, then annually thereafter) and final analysis when all patients have the

opportunity to complete the final study visit. Categorical outcomes will be summarized by the number and percentage of subjects in each category. Continuous outcomes will be summarized by the number of nonmissing values, mean, standard deviation, median, lower and upper quartiles, and minimum and maximum values. For the incidence, 95% confidence interval (CI) will be presented based on an exact method. The analysis will include all enrolled patients (enrollment is triggered once an eligible, consenting patient receives their first dose of Prolia®).

Documents

Study results

Prolia_Abstract_Final_18Dec2020.pdf(100.15 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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