Prospective Observational Study to Describe Characteristics and Management of Patients With Osteoporosis Treated With Prolia® in Routine Clinical Practice in Poland (20160178)

First published: 16/05/2017

Last updated: 26/05/2021

Study Finalised

Administrative details

EU PAS number

EUPAS18916

Study ID

41269

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This is a multi-center, one country, non-interventional, prospective, observational study in osteoporosis patients population who received at least one injection of Prolia® 60 mg Q6M, SC (subcutaneous) in Poland. Prolia® naive patients will be eligible to enroll within 8 weeks after initiation of Prolia® treatment. It is expected that patients will receive their scheduled Prolia® injection every 6 months as part of their routine clinical care. The estimated duration of enrollment is 12 months. No study drug will be administered as part of the study. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. After the initial visit, information regarding Prolia® prescription and administration, procedures pertaining to osteoporosis and Prolia®, concomitant medication use, and non-serious and serious AEs will be collected during routine clinical visits and recorded for up to approximately 12 months after entering the study.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Biotechnologia Sp. z o.o. Amgen Inc. medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Biotechnologia Sp. z o.o. Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/04/2017

Actual: 19/04/2017

Study start date

Planned: 20/10/2017

Actual: 10/07/2017

Data analysis start date

Planned: 31/08/2020

Actual: 03/08/2020

Date of final study report

Planned: 31/01/2021

Actual: 03/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol synopsis_20160178_24Oct2016.pdf(329.27 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

Other

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

Characteristics of patients treated with Prolia in routine clinical practice in Poland during the 12 months of treatment

Data collection methods:

Primary data collection

Main study objective:

The objective of this prospective, observational study in Poland is to describe characteristics of patients treated with Prolia® in routine clinical practice in Poland during the 12 months of treatment

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational study

Study drug and medical condition

Name of medicine

PROLIA

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

Osteoporosis patients population who received at least one injection of Prolia® 60 mg Q6M, SC (subcutaneous) in Poland.

Patients will meet the following inclusion criteria at enrollment into the observational
study:
1. Women with a clinical diagnosis of PMO or men with diagnosis of osteoporosis, have received their first injection of Prolia® within 8 weeks prior to enrolling in this study
2. Decision has been made to treat patient with Prolia® 60 mg once every 6 months
3. Appropriate written informed consent has been obtained

Patients meeting the following exclusion criteria are not eligible to participate in the observational study:
1. Patients who are participating in ongoing or have participated denosumab clinical trials in the past
2. Participation in other clinical or device trials in the last 6 months
3. Contra-indication for treatment with Prolia®

4. Subject has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent.

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)

Estimated number of subjects

600

Study design details

Outcomes

Description of osteoporosis patient population treated with Prolia®: socio-demographic landscape, disease related data, treatment patterns with Prolia®, safety data

Data analysis plan

This is an observational study for which the analysis will be descriptive in nature and no formal hypothesis will be tested.Frequency distributions will be described for categorical variables. Continuous variables will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values

Documents

Study results

20160178 LAST Poland_Clinical Study Report Synopsis_19-May-2021.pdf(806.03 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

Physician’s medical records, 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