Prospective Observational Study to Describe Characteristics and Management of Postmenopausal Women With Osteoporosis Treated With Prolia® in France and its use in Routine Clinical Practice (20130240)

First published: 26/06/2018

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24541

Study ID

29204

DARWIN EU® study

No

Study countries

France

Study description

This is a multicenter, observational and non-interventional study in PMO patients who receiveProlia® (60 mg subcutaneous SC) in France. Patients in the study will be enrolled in 2 waves,each targeting specific aspects of the overall study objectives. The first wave will enrol approximately 500 patients who will be followed for approximately 30 months from the date of enrollment. Patients enrolled in this wave will provide descriptive data on persistence to Prolia® as well as a description of the characteristics of patients being prescribed Prolia®, information regarding Prolia® prescription and administration, and procedures pertaining to Prolia® and safety. The second wave will enroll approximately 250 patients and will only provide a cross-sectional description of the characteristics of patients being prescribed Prolia®

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 94 centers are involved in the study

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: 16/06/2015

Actual: 16/06/2015

Study start date

Planned: 16/06/2015

Actual: 16/06/2015

Data analysis start date

Planned: 21/06/2016

Actual: 27/09/2018

Date of interim report, if expected

Planned: 01/12/2017

Actual: 01/11/2016

Date of final study report

Planned: 26/02/2019

Actual: 22/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS24541-26946.pdf(1.27 MB)

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

NCT02347865

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To evaluate the persistence with Prolia® at 12 months in postmenopausal women with osteoporosis (PMO) in France

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Observational Study

Study drug and medical condition

Name of medicine

PROLIA

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

DENOSUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

Postmenopausal women with osteoporosis who receive a prescription of Prolia® in France.

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

775

Study design details

Outcomes

To evaluate the persistence with Prolia® at 12 months in postmenopausal women with osteoporosis (PMO) in France, To describe the characteristics of PMO women in France treated with Prolia®, the use in routine clinical practice and persistence for two successive years

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Data analysis plan

Analyses are descriptive. In general, data summaries will be presented by wave (ie, wave 1 and 2 will not be combined) and subgroups of interest. Categorical outcomes will be summarized by the number and percentage of patients in each category. Continuous outcomes will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles, and minimum andmaximum values.

Documents

Study results

20130240_Final ORSR Abstract.pdf(747.61 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

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