Prolia® persistence in post-menopausal women with osteoporosis, over 70 years, at increased risk of fracture, treated in routine clinical practice in Bulgaria

First published: 26/05/2017

Last updated: 20/10/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37686

EU PAS number

EUPAS19156

Study ID

37686

DARWIN EU® study

No

Study countries

Bulgaria

Study description

The purpose of this study is to estimate persistence with Prolia® in Prolia® treated at increased risk of fracture postmenopausal women, aged >70 years, at 12, 18 and 24 months in real life clinical practice in Bulgaria. Objective is to estimate the proportion of patient at increased risk of fracture on Prolia® treatment for 2 years. Demographic and clinical characteristics in -increased risk of fracture women >70 years with osteoporosis and treated with Prolia® will be described.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 14 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: 22/03/2017

Actual: 22/03/2017

Study start date

Planned: 14/07/2017

Actual: 11/07/2017

Data analysis start date

Planned: 30/11/2019

Actual: 07/11/2019

Date of final study report

Planned: 20/10/2020

Actual: 20/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol Summary.pdf(208.57 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

Other

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

Persistence to treatment in women at increased risk of fracture

Data collection methods:

Secondary use of data

Main study objective:

To estimate persistence with Prolia® in Prolia treated post-menopausal women with osteoporosis, aged >70 years, at increased risk of fracture, at 12, 18 and 24 months in real life clinical practice in Bulgaria.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

National retrospective and prospective observational study based on clinical data of PMO women at increased risk of fracture receiving treatment with Prolia® for osteoporosis in routine clinical practice in Bulgaria.

Study drug and medical condition

Name of medicine

PROLIA

Medical condition to be studied

Osteoporosis postmenopausal

Population studied

Short description of the study population

Postmenopausal women > 70 years at increased risk of fracture, with/without previous fracture in real life clinical practice referred by orthopedic, neurology or other clinical outpatients and hospital settings to endocrinology and rheumatology centers to be diagnosed with osteoporosis and treated with Prolia® as per specialist’s decision will be included in the study.

Inclusion criteria:

- Women with osteoporosis >70 years old, referred to endocrinologists or rheumatologists by orthopedic, neurology or other clinics/outpatient practices – to be diagnosed with Dual energy X-ray absorptiometry (DXA) and treated with Prolia®
- The patient - meeting FRAX criteria for high risk: either ≥ 3% risk for hip fracture or ≥20% for major osteoporotic fracture
- The patient has received at least 1 Prolia® injection prior to approval of the study by Bulgarian Regulatory Agency and Bulgarian Central Ethics Commission. The date of the approval comes into force when Amgen has been handed the written decisions.

Exclusion criteria:

- Participation in clinical or device trials in the last 6 months
- Patient is currently participating or has participated in Prolia® clinical trials

- Patient is on other anti-osteoporosis medication at the time of enrolment (e.g. oral/i.v. bisphosphonates, or anabolics). Vitamin D and Calcium supplementation are not considered as osteoporosis medication and therefore are permitted.

Age groups

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

250

Study design details

Outcomes

Persistence to Prolia®, time to non-persistence/discontinuation, -Age, age at menopause, prior fragility fracture, prior PMO therapy, history of treatment discontinuation of osteoporosis therapy, FRAX at baseline, -Number of injections received per patient at the end of the study and after 12, 18 and 24 months - Changes from baseline in BMD T-score

Data analysis plan

Baseline characteristics will be summarized using descriptive statistics. Counts and percentages will be provided for categorical outcomes. Continuous outcomes 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

EUPAS19156-37684.pdf(302.63 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical records

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