The use, safety, and effectiveness of Prolia in clinical practice among Chinese women with post-menopausal osteoporosis – Taiwan and Hong Kong (20180325)

First published: 12/11/2018

Last updated: 28/09/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37411

EU PAS number

EUPAS26372

Study ID

37411

DARWIN EU® study

No

Study countries

Hong Kong

Taiwan

Study description

Among Chinese women being treated in clinical practice forpost-menopausal osteoporosis, the objectives are to describe the use of denosumab, characterize the safety of denosumab, and to evaluate the effectiveness of denosumab for the reduction of clinical osteoporotic fractures.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

National Cheng Kung University, Tainan School of pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, The University of Hong

Kong, Hong Kong Centre for Safe Medication Practice and Research, Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine

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: 01/08/2018

Actual: 01/08/2018

Study start date

Planned: 21/01/2019

Actual: 21/01/2019

Data analysis start date
Planned: 21/01/2019

Actual: 21/01/2019

Date of final study report
Planned: 01/08/2020

Actual: 28/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180325_01.02.06 Public Redacted Protocol Ver 1.0 2019-01-02 English.pdf
(609.09 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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Among Chinese women being treated in clinical practice for post-menopausal osteoporosis, the objectives are to:1. Describe the use of denosumab and the patient characteristics2. Characterize the safety of denosumab 3. Evaluate the effectiveness of denosumab for the reduction of clinical osteoporotic fractures

Study Design

Non-interventional study design

Cohort

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 includes women aged 55 years or older (i.e., postmenopausal) who received at least one dose of Prolia. To ensure that included women are receiving Prolia for the indication of PMO, all are excluded with a history of Paget’s disease or malignancy. To be representative of all patients being treated with Prolia in clinical practice, there are no other exclusion criteria.

Inclusion Criteria

- Use of Prolia in clinical practice
- Complete data available on age and sex

Exclusion Criteria

- Males
- Less than 55 years old at initial use of Prolia
- History of any malignancy within 1 year before initial use of Prolia
- History of Paget’s disease within 1 year before initial use of Prolia

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Age groups

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

40000

Study design details

Data analysis plan

Risk estimation

Documents

Study results

01.42.03_csr-20180325-observational research study report- abstract_public-redacted.pdf(1.05 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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