The Safety and Effectiveness of Denosumab Among Chinese With Osteoporosis and Glucocorticoid Exposure – a Real World Study in Taiwan (20220054)

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Study Finalised

Administrative details

EU PAS number

EUPAS49104

Study ID

49446

DARWIN EU® study

No

Study countries

Taiwan

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/09/2022

Actual: 28/09/2022

Study start date
Planned: 01/10/2022

Actual: 01/10/2022

Data analysis start date
Planned: 07/10/2022

Actual: 07/10/2022

Date of final study report
Planned: 31/03/2023

Actual: 24/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to characterize the safety of denosumab among Chinese participants with osteoporosis and glucocorticoid exposure, and to evaluate the effectiveness of denosumab for the reduction of clinical fractures.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medicinal product name

PROLIA

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

The study population comprised of male and female patients aged 18 years or older diagnosed with osteoporosis received treatment with Prolia between 2012 to 2019 identified from the health insurance research database (HIRD) and Chang Gung Research Database (CGRD) of Taiwan.
Inclusion criteria:
1. Eligible patients included all men and women 18 years of age or older who has received their first administration of Prolia between 2012 and 2019 and had at least 2 glucocorticoid prescriptions during their first Prolia dose course.

Exclusion criteria:
1. Patients excluded from the study if they had a history of malignancy or Paget's disease with 1 year before initial use of Prolia.

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

36.000

Study design details

Outcomes

• Effectiveness outcome o Hip fracture • Safety outcomes: o Osteonecrosis of the jaw o Atypical femur fracture o Hypocalcemia, • Effectiveness outcomes: o Clinical vertebral fracture o Non-vertebral fracture (hip, wrist, forearm, humerus)

Data analysis plan

This study includes both a descriptive analysis for safety endpoints and a comparative analysis for effectiveness endpoints

Documents

Study results

20220054 01.47.01.01 Observational Research Study Report Published Report.pdf (107.25 KB)

Data management

Data sources

Data source(s), other

Health Insurance Research Database of the Taiwan Bureau of Health Insurance, Chang Gung Research Database (CGRD) Taiwan

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