Denosumab Global Safety Assessment in Multiple Observational Databases (20090522)

First published: 31/01/2019
Last updated: 14/03/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/38617

EU PAS number
EUPAS27559

Study ID
38617

DARWIN EU® study
No

Study countries
Denmark
Norway
Sweden
United States

Study description
This is a prospective open-cohort study with annual assessment and reporting of descriptive findings from 5 secondary data sources. The study period will include up to 10 years in each data system.

Study status
Ongoing

Research institution and networks

Institutions

Amgen

United States
First published: 01/02/2024
Last updated 21/02/2024

Institution

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden
First published: 24/03/2010
Last updated 23/04/2024

Institution

Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

Aarhus University Hospital

First published: 01/02/2024
Last updated 01/02/2024

Institution

Aarhus University Hospital Denmark, University of Optum Insight USA, University of Alabama at Birmingham USA

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
Actual:
30/12/2009

Study start date
Actual:
26/05/2010

Data analysis start date
Planned:
20/10/2023

Date of interim report, if expected
Planned:
26/11/2019
Actual:
15/05/2019

Date of final study report
Planned:
21/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Other study registration identification numbers and links

NCT02520362

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Main study objective:
Determine incidence rates of adverse events of special interest (AESI) in patients exposed to denosumab, patients exposed to bisphosphonates, and among all women with PMO.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
This is a prospective open-cohort study with annual assessment and reporting of descriptive findings from 5 secondary data sources.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(M05BX04) denosumab

Medical condition to be studied
Osteoporosis

Population studied

Age groups
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
508125

Study design details

Outcomes
Incidence rates of AESI (per 100,000 Person-years) will be assessed in patients exposed to denosumab, patients exposed to biphosphonates, and among all women with PMO

Data analysis plan
Descriptive statistics will be used to characterize exposure cohorts with respect to patient characteristics, clinical features, and AESI risk factors. Person-year adjusted AESI incidence rates will be calculated among exposure cohorts. Exploratory analyses comparing incidence rates of AESI in women with PMO adjusting for potential confounders will also be conducted. Descriptive statistics will be used to characterize denosumab utilization patterns. Descriptive statistics will be used to characterize patients receiving Prolia for unapproved indications.

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)

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