Denosumab Global Safety Assessment in Multiple Observational Databases (20090522)

First published: 31/01/2019

Last updated: 15/11/2024

Study Finalised

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

Finalised

Research institutions 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

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

Actual: 01/04/2023

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

Actual: 15/05/2019

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

Actual: 13/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Amendment denosumab 20090522 13 .pdf(3.01 MB)

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 topic:

Human medicinal product

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

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

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

517991

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.

Documents

Study results

20090522_ORSR_Abstract_13JUL2023_Redacted2.pdf(1.2 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (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