Periodic Knowledge, Attitudes, and Behavior (KAB) Survey of Certified Prescribers to Assess Understanding of the Risks with the Prolia Risk Evaluation and Mitigation of Strategy (REMS) (20240121)

First published: 12/12/2024

Last updated: 09/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000393

Study ID

1000000393

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study will be conducted to survey HCPs who are currently prescribing and those who have the potential to prescribe Prolia, who are part of the REMS Communication Plan outreach, and who have not been debarred or sanctioned in order to assess their awareness and understanding of the risk of severe hypocalcemia with Prolia, the Prolia REMS requirements, and the REMS goals and materials.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

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: 18/09/2024

Actual: 18/09/2024

Study start date

Planned: 12/03/2025

Actual: 07/04/2025

Data analysis start date

Planned: 05/09/2025

Date of final study report

Planned: 05/03/2031

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Protocol-Published Original denosumab 20240121.pdf(1.8 MB)

Protocol-Published Amendment denosumab 20240121 1.pdf(2.37 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

20240121

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

observational, cross-sectional survey of HCPs

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

The objectives of this study are to conduct a survey with HCPs who are currently or have the potential to prescribe Prolia, in order to assess their awareness and understanding of the risk of severe hypocalcemia with Prolia, the Prolia REMS requirements, and the REMS goals and materials.

Main study objective:

To describe HCP knowledge of:

- The risk of severe hypocalcemia in patients with advanced CKD
- The need to assess for presence of CKD-MBD before initiating Prolia

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Name of medicine

PROLIA

Study drug International non-proprietary name (INN) or common name

DENOSUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

Medical condition to be studied

Chronic kidney disease

Population studied

Short description of the study population

HCPs who are currently prescribing and have the potential to prescribe Prolia

Age groups

Adult and elderly population (≥18 years)

Special population of interest

Other

Special population of interest, other

Healthcare providers

Estimated number of subjects

371

Study design details

Setting

Online survey

Comparators

None

Outcomes

The objectives of the HCP KAB survey are to conduct a survey with HCPs identified via Amgen’s database, who are known to be prescribing Prolia, who are part of the REMS Communication Plan outreach, and who have not been debarred or sanctioned in order to assess their awareness and understanding of the risks of Prolia, the Prolia REMS
requirements, and the REMS goals and materials:

• Key Risk Message 1: HCPs must understand the risk of severe hypocalcemia in patients with advanced CKD.

• Key Risk Message 2: HCPs must understand the need to assess for presence of CKD-MBD before initiating Prolia.

Data analysis plan

Statistical analyses will be descriptive in nature. Counts and percentages will be calculated for each question/item in the questionnaire. Ninety-five percent (95%) CIs for the survey end points will be calculated to provide an estimate of

precision; however no formal hypothesis will be tested. All CIs around the percentages will be exact binomial
2-sided 95% CIs calculated according to the method of Clopper-Pearson.
Analyses will be performed at the respondent level; therefore, within-respondent variation is not relevant.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

We are conducting a survey, therefore we are not using any database.

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

Not applicable