Osteoporosis outcomes and treatment patterns in France (20190017)

First published: 22/11/2019

Last updated: 02/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS30506

Study ID

45701

DARWIN EU® study

No

Study countries

☐ France

Study description

This is a retrospective cohort study in the National healthcare data system (Système National des Données de Santée - SNDS) containing French nationwide claims and hospital database including postmenopausal women

receiving treatment for osteoporosis.
The research question is to assess the treatment patterns and the impact of osteoporosis medication on fracture incidence in France.
The primary objective is to assess the change in fracture risk after treatment initiation among post-menopausal women receiving osteoporosis treatment, overall and stratified by type of treatment and type of fracture

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **Not-for-profit** | **ENCePP partner**

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Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Pauline Bosco-Levy (Prince)

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2019

Actual: 28/06/2019

Study start date

Planned: 15/06/2020

Actual: 08/10/2020

Data analysis start date

Planned: 01/08/2020

Actual: 23/03/2021

Date of final study report

Planned: 31/12/2021

Actual: 08/12/2021

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the treatment patterns and the impact of osteoporosis medication on fracture incidence in France

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Osvyrti

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

Short description of the study population

Postmenopausal women receiving treatment for osteoporosis.

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

2000000

Study design details

Outcomes

• To assess the change in fracture risk after treatment initiation among post-menopausal women receiving osteoporosis treatment, overall and stratified by type treatment and type of fracture,
• To describe osteoporosis treatment patterns among post-menopausal women receiving osteoporosis treatment,
• To describe characteristics of post-menopausal women receiving osteoporosis treatment,
• To assess the change in fracture risk after treatment discontinuation among post-menopausal women receiving osteoporosis treatment, overall and stratified by type treatment and type of fracture

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Data analysis plan

• Flow chart for population selection
• Description of baseline characteristics
• Description of drug use by duration of treatment, discontinuation, switching and adherence
• Description of the fracture outcome as the unadjusted risk and rate
• Fracture incidence rate assessed during three periods: 1. Early treatment period (first 3 months post-index, which assumes a delay in fracture reduction following treatment initiation) 2. Treatment exposure period (subsequent time on treatment after the first 3-months post-index, until end of follow up or treatment discontinuation) 3. Post-discontinuation period (period of time with no treatment after treatment discontinuation)
• Fracture incidence rates will be compared between the early treatment period and the treatment exposure period using incidence rate ratios using an own-control analysis
• Fracture incidence rate in the post-discontinuation period will be compared with the early treatment period and treatment exposure period

Documents

Study results

20190017_ORSR_Abstract_24OCT2022_Redacted.pdf (448.64 KB)

Study publications

Bosco-Lévy P, O'Kelly J, Briot K, Mehsen-Cetre N, Fabre A, Lassalle R, et al. E...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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