Observational study assessing incidence of osteosarcoma among Forteo(teriparatide) users by linking state cancer registry data to large national pharmacy database data (B3D-MC-GHBX Addendum 2.3)

First published: 07/04/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18547

Study ID

27245

DARWIN EU® study

No

Study countries

☐ United States

Study description

This cohort study will estimate the incidence rate and IRR for osteosarcoma among adult patients aged ≥18 years treated with Forteo compared to an untreated population. Drug exposure data will be obtained from dispensed pharmacy claims and osteosarcoma diagnosis information will be obtained from state cancer registry files.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicole Kellier-Steele

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/04/2016

Actual: 06/04/2017

Study start date

Planned: 16/01/2017

Actual: 16/01/2017

Data analysis start date

Planned: 03/05/2017

Date of final study report

Planned: 14/09/2017

Actual: 11/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B3D-MC-GHBX Amendment (2.3)(b).pdf(411.62 KB)

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:

Other

If ‘other’, further details on the scope of the study

Observational study

Data collection methods:

Secondary use of data

Main study objective:

To estimate the incidence of osteosarcoma in patients who have received treatment with Forteo over time as compared to a general population comparator cohort using an incidence rate ratio (IRR) and 95% confidence interval (CI).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H05AA02) teriparatide

teriparatide

Medical condition to be studied

Osteosarcoma

Population studied

Short description of the study population

Adult patients aged ≥18 years treated with Forteo were compared to an untreated population.

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)

Estimated number of subjects

477000

Study design details

Outcomes

Incidence of osteosarcoma

Data analysis plan

Incidence rate and IRR for osteosarcoma will be estimated among Forteo users versus matched comparator cohorts. For the primary analysis of each linkage, the IRR and 95% CI for osteosarcoma occurrence in Forteo users and nonusers will be estimated using exact conditional Poisson regression.

Documents

Study results

LY333334 B3D-MC-GHBX 2.3(b) Non-interventional PASS Full Clinical Study Report_Redacted.pdf(4.05 MB)

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 source(s), other

Longitudinal Prescription Data - US, IMS LifeLink: PharMetrics Plus - US

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

Unknown