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
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## Administrative details

EU PAS number	
EUPAS18547	
Charles ID	
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
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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

## 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

# Unknown Check completeness Unknown

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

Unknown