Assessing the Incidence of Osteosarcoma Among Teriparatide Users Using Medicare Part D and State Cancer Registry Data (B3D-MC-GHBX Addendum 2.2)

First published: 07/04/2017
Last updated: 19/02/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/27249

EU PAS number
EUPAS18117

Study ID
27249

DARWIN EU® study
No

Study countries
United States

Study description
This population-based cohort study will utilize secondary data to compare the incidence of osteosarcoma among Forteo users aged 65 years and older with the incidence of osteosarcoma among nonusers aged 65 years and older. Exposure will be ascertained from prescription drug claims, and outcome will be ascertained through linkage with state cancer registries. Forteo users will be matched to nonusers based on demographic and baseline characteristics.

Study status
Finalised

Research institution and networks

Institutions

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
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19/02/2024

Institution
Not-for-profit
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:
18/08/2014
Actual:
18/08/2014

Study start date
Planned:
06/10/2016
Actual:
06/10/2016

Data analysis start date
Planned:
01/05/2017

Date of final study report
Planned:
14/09/2017
Actual:
25/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

GHBX 2_2a.pdf(431.51 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 data collection

Main study objective:
To estimate the incidence rate ratio (IRR) and 95% confidence interval (CI) of osteosarcoma for patients aged 65 years or older with a prescription claim for Forteo versus a cohort of matched comparators.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(H05AA02) teriparatide

Medical condition to be studied
Osteosarcoma

Population studied

Short description of the study population
People enrolled in Medicare Part D. The Forteo (exposed) cohort comprised patients with a health insurance claim for an outpatient medication dispensing of Forteo. These patients wiere individually matched to patients from the general population of Medicare Part D patients with similar demographic and baseline characteristics and with a prescription for a

medication other than Forteo (comparator cohort).

Patients who meet all of the following inclusion criteria in the order below were included:
1. Are aged 65 years or older
2. Have at least 4 months of enrollment prior to first dispensing of Forteo in the exposed cohort (e.g., the index date) or the corresponding index date for the comparator cohort
3. Had 1 or more prescriptions for Forteo during the study period OR are a member of the Medicare Part D general population

Age groups
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
141000

Study design details

Outcomes
Osteosarcoma

Data analysis plan
The primary objective of the study is to estimate the IRR and 95% CI of osteosarcoma for patients aged 65 years or older with a prescription claim for Forteo versus a matched comparison cohort with a prescription claim for a drug other than Forteo. The study uses Medicare Part D prescription drug data to identify the cohort of patients aged 65 years or older who have a claim for Forteo and a cohort of nonusers matched to the Forteo users by age, sex, 2- or 3- digit zip code, calendar month of the qualifying prescription, and number of unique therapeutic classes ofmedications dispensed during the prior 4 months. The outcome of osteosarcoma will be ascertained by linkage of the Medicare Part D study files to the data files from state cancer registries.

Documents

Study results
LY333334 B3D-MC-GHBX Non-interventional PASS Final Study Report Addendum 2.2_Redacted.pdf(717.48 KB)

Data management

Data sources

Data sources (types)
Administrative data (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