Forteo/Forsteo post-approval osteosarcoma surveillance study

First published: 04/02/2015

Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20579

EU PAS number

EUPAS8540

Study ID

20579

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Iceland

☐ Norway

☐ Sweden

Study description

Teriparatide caused dose-dependent increases in the incidence of osteosarcoma in rats during preclinical testing. Studies have shown that the rat skeleton is more sensitive to the pharmacological effects of parathyroid hormone in formation of new bone and osteosarcomathan monkey or human skeletons. Study GHBX has three components: case-finding surveillance in Europe and the United States and a Forteo Patient Registry in the United States. The case-finding surveillance components were designed to identify documented cases of osteosarcoma among men and women aged 40 years and older and determine which cases, if any, had a history of teriparatide treatment. This report contains results of the European case-finding surveillancecomponent.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elizabeth Andrews

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/07/2003

Study start date

Actual: 01/01/2004

Data analysis start date

Actual: 01/01/2004

Date of final study report
Actual: 30/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Company

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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

Case-finding surveillance study

Data collection methods:

Secondary use of data

Main study objective:

The primary objective was to identify newly diagnosed cases of osteosarcoma among men and women aged 40 years or older in selected countries and identify incident osteosarcoma cases with a history of teriparatide treatment. The secondary objective was to collectadditional patient information and data related to other risk factors for osteosarcoma.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-finding surveillance study

Study drug and medical condition

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

TERIPARATIDE

Medical condition to be studied

Osteosarcoma

Population studied

Short description of the study population

Men and women aged 40 years or older at the time of diagnosis and had histological confirmation of osteosarcoma or one of five other tumour types with a primary bone site were identified through the Scandinavian Sarcoma Group (SSG) registry and the Finnish and Swedish National Cancer Registries.

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Osteosarcoma patients

Estimated number of subjects

112

Study design details

Outcomes

Osteosarcoma

Data analysis plan

The analysis compared the observed number of patients with osteosarcoma(OS) with a possible or confirmed exposure to teriparatide to the number of exposed OS cases expected to be identified by cancer registries. The number of patients treated with teriparatide expected tobe diagnosed with OS was calculated using the estimated size of the exposed population and background rate for OS in the Nordic countries (i.e. assuming no association between drug exposure and disease). The incidence rate for OS was generated from population estimates foreach country, as well as published population-based OS incidence. Population estimates for adults aged 40+ yrs were based on national statistics data for each country. Because this population grew from approximately 12 million in 2004 to 13.24 million in 2013, the population at the approximate midpoint of the study (2008), 12.6 million people aged 40+ yrs, was used for relevant estimates.

Documents

Study results

GHBX_Nordic Country FSR_PASS.pdf(246.74 KB)

Study publications

Andrews EB, Gilsenan AW, Midkiff K, Sherrill B, Wu Y,Mann BH, et al. The US pos…

von Scheele B, Martin RD, Gilsenan AW, Ceberg J, Andrews EB, Masica D, Alvegård…

Data management

Data sources

Data source(s), other

Scandinavian Sarcoma Group Denmark, Scandinavian Sarcoma Group Finland, Scandinavian Sarcoma Group Iceland, Scandinavian Sarcoma Group Norway, Scandinavian Sarcoma Group Sweden

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Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

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