Cohort Study of Venous Thromboembolism and Other Clinical Endpoints among Osteoporotic Women Prescribed Bazedoxifene, Bisphosphonates or Raloxifene in Europe

First published: 12/12/2013
Last updated: 30/11/2020





Administrative details

EU PAS number	
EUPAS5395	
Study ID	
Study ID	
38352	
DARWIN EU® study	
No	
Study countries	
Italy	
Spain	

Study status

Finalised

Research institutions and networks

Institutions

Cegedim Health Data (CHD)
France
First published: 01/02/2024
Last updated: 01/02/2024
Institution Other ENCePP partner

Contact details

Study institution contact

Kofi Asomaning kofi.asomaning@pfizer.com

Study contact

kofi.asomaning@pfizer.com

Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/09/2011

Study start date

Actual: 01/01/2012

Data analysis start date

Planned: 30/04/2019

Date of interim report, if expected

Planned: 30/04/2016

Actual: 22/04/2016

Date of final study report

Planned: 30/04/2020 Actual: 30/04/2020

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

BZA EU PASS_Final_AUG 2013 GDMS_clean.pdf (386.57 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To estimate and compare the incidence rates of venous thromboembolism (VTE) among women receiving bazedoxifene and women receiving a bisphosphonate for treatment of osteoporosis.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-authorization safety study

Study drug and medical condition

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

Population studied

Short description of the study population

All women in the Cegedim database meeting the inclusion criteria will be included in the analysis without any sampling process.

Inclusion Criteria

Subjects must meet all of the following inclusion criteria to be eligible for inclusion into the study:

- 1. Female
- 2. At least one prescription for bazedoxifene, raloxifene, or any bisphosphonate during the study inclusion period (index prescription);
- 3. A recoded diagnosis code of osteoporosis on or within 60 days prior to the index prescription date;
- 4. Age >=45 at the date of the index prescription; and
- 5. At least 6-months of follow-up data in the electronic medical record system prior to the date of the index prescription

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

2150

Study design details

Outcomes

Venous thromboembolism (VTE), • Ischemic stroke• Thrombotic and ischemic cardiac disorders (including myocardial infarction, myocardial ischemia, and coronary occlusion)• Atrial fibrillation• Biliary events: cholecystitis, cholelithiasis• Hypertriglyceridemia • Fractures• Chronic and acute renal failure (including chronic renal insufficiency and end stage renal disease)• Malignancies including breast, renal, ovar

Data analysis plan

Incidence rates will be calculated for all endpoints in all treatment groups, incidence rate ratios and 95% confidence intervals will be calculated and compared. Stratifications by risk factors of interest

Documents

Study results

B1781044_Bazedoxifene_Final_Study_Report_ABSTRACT_24April2020 V1.pdf (60.98 KB)

Study report

B1781044 Bazedoxifene Final Study Report 24April2020 V1.pdf (519.49 KB)

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

Cegedim Longitudinal Patient Database (LPD) Italy, Cegedim Longitudinal Patient Database (LPD) Spain

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No