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

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38352

EU PAS number

EUPAS5395

Study ID

38352

DARWIN EU® study

No

Study countries

☐ Italy

☐ Spain

Study status

Finalised

Research institutions and networks

Institutions

Cegedim Health Data (CHD)

☐ France

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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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 name

BAZEDOXIFENE

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

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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

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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

Data sources

Data source(s), other

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

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Data sources (types)

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