# 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

**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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution | Other | ENCePP partner

## Contact details

**Study institution contact**

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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

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**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

**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

**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