Drug Utilisation Study of conjugated oestrogens/bazedoxifene (CE/BZA) in the European Union (EU)

First published: 17/11/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11604

Study ID

35301

DARWIN EU® study

No

Study countries

- Belgium
- Finland
- France
- Germany

Italy

Netherlands

Spain

Sweden

United Kingdom

Study description

Describe baseline characteristics and utilisation patterns of EU patients initiating Duavive or oestrogen + progestin (E+P) combination hormone replacement therapy (HRT), in all EU countries where CE/BZA is commercially available in 2016-2017.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vera Frajzyngier

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/04/2015

Actual: 24/04/2015

Study start date

Planned: 22/10/2017

Actual: 22/10/2017

Data analysis start date

Planned: 30/09/2017

Date of interim report, if expected

Planned: 31/03/2018

Date of final study report

Planned: 31/03/2020

Actual: 31/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

B2311061_Duavive EU DUS FINAL Protocol CHMP ENDORSED OCT2015.pdf (917.89 KB)

b2311061 protocol amendment.pdf (2.43 MB)

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The overall aim of this drug utilization study (DUS) is to describe the baseline characteristics and utilization patterns of EU patients initiating either Duavive or oestrogen + progestin hormone replacement therapy (E+P HRT).

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

DUAVIVE

Medical condition to be studied

Menopausal symptoms

Population studied

Short description of the study population

Study subjects are all patients identified in the respective databases with at least one prescription for Duavive or E+P HRT during the defined study period. Patients must meet both of the following inclusion criteria to be eligible for this study:

1. All patients identified in the respective databases who have received at least one prescription for Duavive or E+P HRT during the 3 years following the first EU launch of Duavive will be included.
2. Patients need to be enrolled in the data source for at least 12 months prior to their earliest prescription of either Duavive or an (E+P) HRT comparator.

Patients with less than 12 months of database enrolment prior to their index prescription will be excluded.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

999

Study design details

Data analysis plan

Among Duavive or E+P HRT users, analyses will be descriptive in nature, performed annually for 3 years, and use counts and percentages for categorical variables and means ±with standard deviations for continuous variables. Data from each EU country will be analyzed separately, and may be pooled when feasible, and results will be compared descriptively across countries. Once multiple years of data are available, trends over time will also be reported. The demographics (age, body mass index BMI) and clinical characteristics (co-morbidities, concomitant medications, medical and drug history) of patients identified to have received a Duavive or E+P HRT prescription will be summarized from their 12 month period prior to treatment initiation (pre-index) and compared. The proportions of Duavive patients with possible off-label use will be described.

Documents

Study results

b2311061-EU DUS_smaller.pdf (1.73 MB)

Study, other information

Annex 1_Duavive EU DUS_FINAL CHMP ENDORSED OCT2015.pdf (731.74 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)

THIN® (The Health Improvement Network®)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Longitudinal Patient Data - France

Longitudinal Patient Data Spain - OMOP

IQVIA Longitudinal Patient Data - Belgium

Data source(s), other

Longitudinal Prescription Data - Netherlands

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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