A retrospective longitudinal cohort study assessing the safety of Seasonique® use: A post-marketing authorization safety study (PASS) to assess the risk of venous thromboembolic events (VTE) in women exposed to Seasonique®

First published: 08/05/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18976

Study ID

33612

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational retrospective cohort study to assess the safety of Seasonique® use during standard clinical practice. The study participants will consist of females using Seasonique® during the study period. The study population will be identified from an existing US health care database.

Study status

Finalised

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

John Seeger

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 21/04/2017

Actual: 21/04/2017

Study start date
Planned: 09/05/2017

Actual: 09/05/2017

Date of final study report
Planned: 09/11/2019

Actual: 23/09/2019

Sources of funding

- Pharmaceutical company and other private sector
- Non-for-profit organisation (e.g. charity)

More details on funding

Teva Pharmaceutical LTD, Theramex Ireland Limited

Study protocol

2017-2-7_Seasonique -PASS Protocol V 5.2- Updated- CLEAN.pdf(572.8 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

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 assess the safety of Seasonique® use during standard clinical practice

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LEVONORGESTREL

ETHINYLESTRADIOL

Population studied

Short description of the study population

Women who have a record of at least one prescription dispensed for SEASONIQUE or 28-day cycle COCLNG (comparator) during the study period were included.

Patients were included in the study only if they meet all of the following criteria:

• Have a record of at least one prescription dispensed for SEASONIQUE or 28-day cycle COCLNG during the study period

• At least 12 months of continuous membership enrolment prior to first COC prescription

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

100000

Study design details

Outcomes

To evaluate the incidence rate of VTE in women exposed to Seasonique®, To evaluate the incidence rates of other CV events and gynaecological outcomes

Data analysis plan

Risk will be estimated using Cox proportional hazards models, with adjustment for covariates.

Documents

Study results

Results summary for EU PASS register 12FEB2020.pdf(17.9 KB)

Study report

98165 Seasonique Revised Final Report 23SEP2019 full.pdf(3.69 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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