Observational Studies to Assess Maternal and Fetal Outcomes Following Exposure to Duloxetine (F1J-MC-B057)

First published: 25/10/2016

Last updated: 12/11/2019

Study Finalised

Administrative details

EU PAS number

EUPAS15946

Study ID

32283

DARWIN EU® study

No

Study countries

United States

Study description

The study was designed to assess the risk of major congenital malformations, preterm delivery, small for gestational age, and preeclampsia associated with duloxetine use in pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Brigham and Women's Hospital

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hu Li

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2016

Actual: 14/04/2016

Study start date
Planned: 01/11/2016

Actual: 01/11/2016

Data analysis start date
Planned: 01/12/2016

Date of final study report
Planned: 31/10/2018

Actual: 30/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and company

Study protocol

LY248686 F1J-MC-B057 Non-interventional PASS Protocol.pdf (601.26 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

Disease /health condition

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 duloxetine for the developing fetus. Specifically:• To assess the safety of duloxetine for the developing fetus. • To assess the safety

of duloxetine for the pregnant woman.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Exposure during pregnancy

Population studied

Short description of the study population

Publicly insured pregnant women 18 to 55 years of age.

Inclusion criteria:
i. Base cohort to include pregnancies drawn from the MAX database with linked offspring from 2004 to 2013
ii. Maternal eligibility for Medicaid from 3 months prior to the LMP until 1 month post delivery
iii. Offspring eligibility from months 1 to 3 after the delivery, unless the infant died prior to the end of the 3 months, in which case a shorter eligibility period until death were permitted

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Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

1400

Study design details

Outcomes

Major congenital malformations, Postpartum haemorrhage, Preeclampsia, Small for gestational age, Preterm delivery, and non-live birth.

Data analysis plan

Results will be presented for four levels of adjustment: (i) unadjusted, (ii) restricted to women with recorded depression, anxiety, specific pain conditions to control for the potential effect of the underlying illness or factors associated with it, using PS stratification to account for imbalances in the specific indication, (iii) restricted to women with a recorded diagnosis of the indications, using PS stratification to further control for imbalances in the specific indication, proxies of severity of the underlying indication and other potential confounders128, and (iv) restricted to women with a recorded diagnosis of the indications, using high-dimensional propensity score (hdPS) stratification to further reduce residual confounding by controlling for proxies of unmeasured confounders.

Documents

Study results

B057 PASS Final Study Report_Redacted.pdf (7.69 MB)

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 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