

# 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.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Brigham and Women's Hospital

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

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

Institution

## Contact details

### Study institution contact

Hu Li [li\\_hu\\_hl@lilly.com](mailto:li_hu_hl@lilly.com)

Study contact

[li\\_hu\\_hl@lilly.com](mailto:li_hu_hl@lilly.com)

### Primary lead investigator

Hu Li

## Study timelines

### **Date when funding contract was signed**

Planned: 01/11/2016

Actual: 14/04/2016

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### **Study start date**

Planned: 01/11/2016

Actual: 01/11/2016

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### **Data analysis start date**

Planned: 01/12/2016

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### **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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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)

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## Special population of interest

Pregnant women

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## 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.

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## 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 confounders<sup>128</sup>, 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)

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## Data management

### 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

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#### Check completeness

Unknown

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#### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No