

# Pregnancy outcome following maternal exposure to mirtazapine: a collaborative ENTIS study

**First published:** 13/08/2012

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/9839>

### EU PAS number

EUPAS2884

### Study ID

9839

### DARWIN EU® study

No

### Study countries

☐ Czechia

- ☐ Finland
  - ☐ Israel
  - ☐ Italy
  - ☐ Netherlands
  - ☐ Switzerland
  - ☐ Türkiye
  - ☐ United Kingdom
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### Study description

Observational prospective cohort study comparing pregnancy outcomes after exposure to mirtazapine with two matched control groups: exposure to any selective serotonin reuptake inhibitor (SSRI), and general controls without any exposure to medication known to be teratogenic or to any antidepressant.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Swiss Teratogen Information Service

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Institution

Multiple centres: 11 centres are involved in the study

## Networks

### European Network of Teratology Information Services (ENTIS)

- ☐ Austria
- ☐ Czechia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Italy
- ☐ Netherlands
- ☐ Spain
- ☐ Switzerland
- ☐ United Kingdom

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Network

ENCePP partner

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Ursula Winterfeld

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/08/2012

Actual: 01/08/2012

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**Study start date**

Planned: 03/10/2011

Actual: 03/10/2011

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**Date of final study report**

Planned: 30/04/2015

Actual: 01/06/2015

## Sources of funding

- Pharmaceutical company and other private sector

- Non-for-profit organisation (e.g. charity)
- EU institutional research programme
- Other

## More details on funding

No funding

## Regulatory

**Was the study required by a regulatory body?**

No

## 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:**

Primary data collection

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**Main study objective:**

The aim of the study is to assess the risk of mirtazapine exposure during pregnancy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

MIRTAZAPINE

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**Anatomical Therapeutic Chemical (ATC) code**

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

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**Medical condition to be studied**

Pregnancy

## Population studied

## **Short description of the study population**

Pregnant women with or without exposure to mirtazapine.

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## **Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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## **Special population of interest**

Pregnant women

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## **Estimated number of subjects**

1071

# **Study design details**

## **Outcomes**

The primary objective is to prospectively evaluate the rate of major birth defects after first trimester exposure to mirtazapine. Secondary objectives are to evaluate pregnancy outcome, birth weight, gestational age at delivery, and neonatal outcome of prospectively collected exposures to mirtazapine at any time during pregnancy.

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## **Data analysis plan**

The birth defect rates will be calculated taking live births and anomalies in elective terminations of pregnancies (ETOPs) and miscarriages into account. Crude miscarriage rates will be calculated per exposed pregnancies or controls and after exclusion of ETOPs. Miscarriage rates will also be calculated applying the method of cumulative incidence function. Outcome endpoints of interests between the case and control groups will be compared using Chi Square or Fisher's exact tests for categorical data and Kruskal-Wallis (for three groups) or

Mann-Whitney tests (for two groups). Further multivariate explorations will rely on logistic regression analysis to account for a possible role of cofactors (dosage level, exposure time and duration, maternal age, alcohol, tobacco).

## Data management

### Data sources

#### Data sources (types)

Other

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#### Data sources (types), other

Prospective patient-based data collection

### 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