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

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.

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

Study start date

Planned: 03/10/2011

Actual: 03/10/2011

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

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

Anatomical Therapeutic Chemical (ATC) code

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

Pregnant women with or without exposure to mirtazapine.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Special population of interest

Pregnant women

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.

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No