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 institution and networks

Institutions

Swiss Teratogen Information Service
First published: 01/02/2024
Last updated 01/02/2024
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
First published: 31/05/2010
Last updated 13/05/2024
Network
ENCePP partner

Contact details

Study institution contact

Ursula Winterfeld
Study contact

ursula.winterfeld@chuv.ch
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

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