Assessment of Pregnancy Outcomes in Women Exposed to Modafinil/Armodafinil: Pregnancy Database Study

First published: 07/10/2021

Last updated: 19/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45563

EU PAS number

EUPAS43538

Study ID

45563

DARWIN EU® study

No

Study countries

☐ France

United States

Study status

Ongoing

Research institutions and networks

Institutions

IBM Watson

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Sigal Kaplan

Study contact

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Primary lead investigator

Sigal Kaplan

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 16/07/2020

Study start date
Planned: 31/12/2021

Actual: 23/11/2021

Date of final study report
Planned: 31/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Branded Pharmaceutical Products R&D, Inc.

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

to estimate the prevalence of pregnancy outcomes, including maternal and fetal outcomes, in women exposed to modafinil/armodafinil during pregnancy, compared to an unexposed cohort

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

MODAFINIL

ARMODAFINIL

Medical condition to be studied

Pregnancy

Exposure during pregnancy

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1000

Study design details

Outcomes

major congenital malformation, spontaneous abortions, stillbirths, low birth weight and small for gestational age births/intrauterine growth retardation/failure to thrive, preterm delivery

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Data analysis plan

Study data will be summarized using descriptive statistics. The prevalence of major congenital malformations will be calculated as the number of total major congenital malformations out of the total number of births. Analysis of the primary endpoint, major congenital malformations, and other secondary endpoints will be performed using proportions with 2 sided 95% CI, as applicable. Comparisons of pregnancy outcome rates will be made between modafinil/armodafinil exposed women and the comparison cohort. For the comparisons, the point estimates of relative risks with 95% CIs and nominal p values will be reported. If feasible, an adjusted relative risk ratio for major congenital malformations among modafinil/armodafinil exposed women

compared to unexposed women will be estimated using a logistic regression model adjusting for other confounding factors such as maternal age, and year of pregnancy.

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

SIDIAP

Data sources (types)

Administrative healthcare records (e.g., claims)

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