Antidepressants during pregnancy: a French drug utilisation study in EFEMERIS cohort

First published: 23/11/2018

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS26684

Study ID

26685

DARWIN EU® study

No

Study countries

France

Study description

Previous studies have suggested that exposure to some antidepressants (AD) during pregnancy could be associated with an increased risk of congenital malformations and neurodevelopment disorders for the child. We conducted a study to describe the use of AD during pregnancy in France.We performed a drug utilisation study in EFEMERIS, a French cohort of pregnant women. At the time of the present study, 89,170 pregnant women, who were pregnant from 2005 to 2014 in Haute-Garonne were included.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Contact details

Study institution contact

Christine Damase-Michel christine.damase-michel@univ-tlse3.fr

Study contact

christine.damase-michel@univ-tlse3.fr

Primary lead investigator

Christine Damase-Michel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2016

Actual: 15/09/2016

Study start date

Planned: 01/10/2016

Actual: 01/10/2016

Date of final study report

Planned: 01/01/2018

Actual: 01/01/2018

Sources of funding

- Other

More details on funding

ANSM

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective is to describe the use of antidepressants during pregnancy in France.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AA) Non-selective monoamine reuptake inhibitors

Non-selective monoamine reuptake inhibitors

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

(N06AF) Monoamine oxidase inhibitors, non-selective

Monoamine oxidase inhibitors, non-selective

(N06AG) Monoamine oxidase A inhibitors

Monoamine oxidase A inhibitors

(N06AX) Other antidepressants

Other antidepressants

Medical condition to be studied

Depression

Population studied

Short description of the study population

Pregnant women, who were pregnant from 2005 to 2014 in Haute-Garonne.

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

89.000

Study design details

Outcomes

Dispensation of antidepressant drugs.

Data analysis plan

Prevalence and incidence of AD prescriptions during pregnancy, characteristics of AD users, and trends in AD use over the 10-year period were studied.

Documents

Study publications

Hurault-Delarue C, Lacroix I, Bénard-Laribière A, Montastruc JL, Pariente A, Da…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

EFEMERIS

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

Unknown