

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

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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.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Pharmacologie En Population cohorteS biobanquesS (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

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Study contact

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**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

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**Study start date**

Planned: 01/10/2016

Actual: 01/10/2016

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**Date of final study report**

Planned: 01/01/2018

Actual: 01/01/2018

## Sources of funding

- Other

More details on funding

## Regulatory

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

Yes

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

**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

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**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.

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## Age groups

- Adults (18 to < 46 years)

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## Special population of interest

Pregnant women

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## Estimated number of subjects

89000

# Study design details

## Outcomes

Dispensation of antidepressant drugs.

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## 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-Larivière 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

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### 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

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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**

Unknown