# How to classify women exposed to drug prescriptions during pregnancy in pharmaco-epidemiology studies? Method using treatment intensity and individual trajectories of exposure over time

**First published:** 21/11/2014

**Last updated:** 01/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS8001

**Study ID**

26677

**DARWIN EU® study**

No

**Study countries**

☐ France

**Study description**

Pregnancy represents a situation in which the dose, the duration and the period of exposure play an essential role in the occurrence of adverse effects on the newborn. However, these parameters are often insufficiently and inconsistently addressed. Therefore, it is necessary to develop new methods in order to take into account more precisely exposure profiles to drugs during pregnancy in pharmaco-epidemiology studies. The objective of the present study is to propose a new method to classify women according to drug exposure during pregnancy taking into account treatment intensity, duration and evolution.We will apply this method to psychotropic drugs during pregnancy in EFEMERIS.

**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**

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**Primary lead investigator**

Christine Damase-Michel

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 14/09/2012

**Study start date**

Actual: 15/11/2012

**Data analysis start date**

Actual: 15/01/2013

**Date of final study report**

Planned: 02/11/2015

Actual: 03/12/2015

## Sources of funding

- Other

## More details on funding

ANSM - PHRC

## Regulatory

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

No

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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:**

Not applicable

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**Main study objective:**

The objective of the present study is to propose a new method to classify women according to drug exposure during pregnancy taking into account treatment intensity, duration and evolution.We will apply this method to psychotropic drugs during pregnancy in EFEMERIS.

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N05) PSYCHOLEPTICS

PSYCHOLEPTICS

(N06) PSYCHOANALEPTICS

PSYCHOANALEPTICS

## Population studied

**Short description of the study population**

Women exposed to psychotropic drugs during pregnancy in EFEMERIS database.

**Age groups**

Adults (18 to < 46 years)

**Special population of interest**

Pregnant women

**Estimated number of subjects**

3700

## Study design details

**Data analysis plan**

With the proposed method, pregnant women are classified according to drug exposure taking into account treatment intensity and prescription evolution during pregnancy. Three steps are required to set up the new method : 1.Convertion of filled prescriptions into exposure variables (using ATC-DDD) 2.Construction of individual trajectories of exposure 3.Classification of individual trajectories of exposure in homogeneous groups.

## Documents

**Study publications**

Hurault-Delarue C, Chouquet C, Savy N, Lacroix I, Beau AB, Montastruc JL, Damas...

# Data management

## 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