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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Study 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

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:

Not applicable

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

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