Assessing exposure to cardiovascular therapy, anxiety depressive syndrome treatment and anti-infectives during pregnancy and breastfeeding (Drug exposure in pregnancy and breastfeeding)

First published: 20/10/2020

Last updated: 01/02/2023

Study | Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103358

EU PAS number

EUPAS37675

Study ID

103358

DARWIN EU® study

No

Study countries

Spain

Study description

Pharmacotherapy during pregnancy and breastfeeding implies the possible risk of congenital disorders and other diseases in the offspring, so it is necessary to assess the benefit-risk balance of all drug treatments before prescribing them in pregnant or breastfeeding women. The drug use in pregnancy and breastfeeding has been assessed through different studies and, lately, through database studies, which offer advantages such as linked information mother-offspring, long-term follow-up periods for mothers and infants, information on maternal and birth outcomes, and information on confounding factors. The use of drugs during pregnancy and breastfeeding has not been assessed through electronic health records in our setting and we plan to assess it through a population based study conducted with SIDIAP data in all women with pregnancy and breastfeeding registered in this database throughout 2011-2020. We plan to analyse drug use during pregnancy and breastfeeding, focalising in cardiovascular, neurologic and psychiatric disorders, to analyse vaccines use during these periods, and to detect possible congenital disorders and other diseases during childhood which may be caused by drug exposures of the mothers during pregnancy and breastfeeding.

Study status

Finalised

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ainhoa Gomez-Lumbreras

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/09/2019

Actual: 01/09/2020

Study start date
Planned: 01/10/2019

Actual: 20/07/2020

Data analysis start date
Planned: 02/11/2020

Actual: 01/01/2021

Date of final study report
Planned: 30/12/2022

Actual: 30/06/2022

Sources of funding

- Other

More details on funding

IDIAPJGol

Study protocol

ProtocolAjutsIDIAP_PREGNANCYesmena_20200709_v2-clean.pdf(908.82 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

a) To analyse drug use during pregnancy b) To analyse drug use during breastfeeding c) To analyse diagnoses in the offspring of mothers with drug exposure during pregnancy and breastfeeding d) To analyse SARS-Co-V2 infection in pregnant women

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Population-based observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C01BA) Antiarrhythmics, class Ia

Antiarrhythmics, class Ia

(C07FB) Beta blocking agents and calcium channel blockers

Beta blocking agents and calcium channel blockers

(C08E) NON-SELECTIVE CALCIUM CHANNEL BLOCKERS

NON-SELECTIVE CALCIUM CHANNEL BLOCKERS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N05B) ANXIOLYTICS

ANXIOLYTICS

Population studied

Short description of the study population

The study population involved pregnant women aged 12-50 years and their offspring identified from the SIDIAP database during the study period of 2011 to 2020.

Inclusion criteria:

- Women from 12-50 years
- Women identified with a pregnancy code during the study period (2011-2020)
- Women with at least one visit registered in primary care/ASSIR during the study period

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Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

200000

Study design details

Data analysis plan

All processes of data management and statistical analysis will be carried out using statistical package R 3.3 (2016). At the exploratory level, the demographic data and baseline characteristics of the study population will be described using relative and absolute frequencies for the categorical and mean variables, standard or median deviation and interquartile range for the continuous variables. In the bivariate analysis, we will consider the Chi-square test or the Fischer exact test for categorical variables and the Student t test or Mann-Whitney U test for continuous variables according to their distribution. The evaluation of mothers' drugs exposures and the risk of diseases and congenital outcomes in their offspring will be carried out by means of multiple

logistic regression models or proportional risk models (Cox). The adjustment for risk factors will be determined based on the characteristics of the study population.

Documents

Study results

IMP-210-CT V01 Mem Final Ajuts IDIAP - Projecte SIDIAP_DEDPAB_20220516.pdf (504.46 KB)

Study publications

Maria Giner-Soriano, Marta Lestón Vázquez, Ainhoa Gomez-Lumbreras, Oriol Prat-V…

Marta Lestón Vázquez, Maria Giner-Soriano, Oriol Prat Vallverdú, Ainhoa Gomez-L…

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

SIDIAP

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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