Uso de fármacos en mujeres embarazadas y lactantes. Consecuencias en la salud de estas mujeres y en la de su descendencia (Drug use in pregnant and breastfeeding women. Outcomes in the health of the women and the offspring) (Drug use during pregnancy and breastfeeding)

First published: 25/05/2022

Last updated: 09/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS47450

Study ID

48065

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Drug use during pregnancy and breastfeeding is frequent to treat chronic and acute conditions. However, information on use, safety or effectiveness of drugs in these women is not routinely available due to limited access to participation of pregnant and lactating women in clinical trials for ethical concerns, making it difficult to assess benefits and risks of drug exposure of these women in their own health and in their offspring. The European Medicines Agency (EMA) Good Pharmacovigilance Practices indicate that it is necessary to conduct post-authorisation safety studies for those drugs which cannot be discontinued during gestation, those used for pregnancy or breastfeeding-related conditions or those associated with any risk for the offspring in the preclinical studies. In recent years, health care databases have made possible to conduct pharmacoepidemiological studies to assess drug exposure during pregnancy and breastfeeding and, through the mother-offspring linkage, to study health problems in the offspring which might be caused by their mother exposure. Our objective is to analyze drug use during these periods through a population-based cohort study with SIDIAP data, including women who are pregnant and breastfeeding, and to detect possible congenital anomalies and other health problems at birth and childhood which may have been caused by mothers' drug exposure during pregnancy and breastfeeding. We also aim to explore beliefs, experiences and attitudes on drug use during pregnancy and breastfeeding from the women's perspective and their partners and from the health professionals' perspective through a qualitative exploratory study and an observational descriptive study by means of questionnaires, in order to detect if there are false beliefs on the risk or safety of medicines. Thus, we can add evidence to improve the evaluation of the benefit-risk balance of pharmacological treatments to support clinicians in their management and

treatment practices.

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: 23/05/2025

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

Institut Català de la Salut (ICS)

First published: 01/02/2024

Last updated: 01/02/2024

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

Contact details

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Study timelines

Date when funding contract was signed

Planned: 02/05/2022

Study start date

Planned: 01/09/2022

Data analysis start date

Planned: 31/01/2023

Date of final study report

Planned: 31/01/2025

Actual: 31/01/2025

Sources of funding

- Other

More details on funding

Pla estratègic de recerca i innovació en salut, PERIS 2022-2024. Generalitat de Catalunya, Departament de Salut. SLT0021/21/000068

Study protocol

PROTOCOL_DefPERIS_20220204.pdf (864.03 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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Objective 1: Cohort study

Objective 2: Qualitative study

Objective 3: Observational study (survey)

Main study objective:

To describe use of drugs, supplements and vaccines during pregnancy and breastfeeding and the effects of this use on the health of women and their offspring.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Cohort + qualitative study + survey

Population studied

Short description of the study population

Pregnant and lactating population, children

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

300000

Study design details

Setting

Primary Health Care, pregnant population, lactating population, offspring

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Outcomes

Effects of the drug use on the health of pregnant and lactating women and of their offspring.

To develop an algorithm to identify lactation periods in women and children through electronic health records.

To describe drug use in pregnancy and breastfeeding.

To explore beliefs, experiences and attitudes over the drug use during pregnancy and breastfeeding from the women's perspective, their partners and the health professionals who attend them.

Data analysis plan

To determine exposure to the drugs of interest during the different phases of the study we will use non-parametric models to estimate the most likely treatment using of electronic prescription and/or pharmacy dispensing records.
Baseline socio-demographic and clinical data of the study population will be described by absolute and relative frequencies for categorical variables and by mean and standard deviation or median and interquartile range for continuous variables.
In univariate models, the chi-square test or Fisher's exact test will be used for categorical variables and the Student's t-test or Mann-Whitney U-test for continuous variables.
The assessment of maternal drug exposure and the risk of diseases and congenital abnormalities in offspring will be performed using logistic relative risk models. Adjustment for risk factors will be determined according to the characteristics of the study population.

Summary results

We developed an algorithm to automatically identify the pregnancy periods in SIDIAP. We identified 327865 pregnancy episodes in 250910 people from January 2011 to June 2020.
We described prescription drugs used during pregnancy.
The most used ones were supplements, analgesics, NSAID or antibiotics. SIDIAP might be an efficient database to study drug safety during pregnancy and the consequences of drug use in the offspring.
We have developed two qualitative studies, where we have interviewed pregnant and lactating women, their partners and health professionals.

Documents

Study results

Pregnancy algorithm_BMJOpen2023.pdf (937.63 KB)

gomez-lumbreras-et-al-2024-drug-exposure-during-pregnancy-a-case-control-study-from-a-primary-care-database.pdf (634.02 KB)

fphar-15-1346357.pdf (1.02 MB)

e085167.full_.pdf (635.06 KB)

Study report

memòria HMA-EMA.pdf (1.04 MB)

Study publications

Ainhoa Gomez-Lumbreras, Marta Leston Vazquez, Carles Vilaplana-Carnerero, Oriol…

Marta Lestón Vázquez, Carles Vilaplana-Carnerero, Ainhoa Gomez-Lumbreras, Oriol…

Lucía Bellas, Lina Camacho-Arteaga, Maria Giner-Soriano, Albert Prats-Uribe, Cr…

Ainhoa Gomez-Lumbreras, Carles Vilaplana-Carnerero, Marta Leston Vazquez, Crist…

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)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

The study consists in three substudies: 1. Cohort study in SIDIAP databases 2. Qualitative study including pregnant and breastfeeding women, their partners, and health professionals attending those women 3. Observational study through survey data collected from pregnant and breastfeeding women

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