

# Asthma medication during pregnancy : a cohort study in EFEMERIS

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

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7994

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### Study ID

17493

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

Asthma affects around 8% of pregnant women. Studies show that women experience changes in prescriptions for asthma medications during pregnancy, maybe because of concerns about their possible adverse effects on the fetus.

The objective of the study is to describe asthma medications before and during pregnancy in France and to assess the possible association between asthma medications and adverse pregnancy outcomes. Women from EFEMERIS, a French database including prescribed and dispensed reimbursed drugs during pregnancy and pregnancy outcomes, who delivered between July 1, 2005 and December 31, 2012 will be included. Women with at least 2 dispensations for any asthma medication (ATC code R03) from the 30 days prior to conception through their date of delivery will be considered asthmatic. First, a description of prescription of asthma medications will be made. Second, we will compare pregnancy outcomes and newborn health between asthmatic and non-asthmatic women.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

 France

**First published:** 31/03/2022

**Last updated:** 01/07/2024

**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: 01/01/2015

Actual: 01/01/2015

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### Study start date

Planned: 01/01/2015

Actual: 01/01/2015

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### Date of final study report

Planned: 31/12/2016

Actual: 31/12/2016

## Sources of funding

- Other

## More details on funding

Agence Nationale de Sécurité des Médicaments et produits de santé (ANSM),  
Clinical Research Hospital Program

## 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:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The aim of the study is to describe asthma medications before and during pregnancy in France and to assess the possible association between asthma medications and adverse pregnancy outcomes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

## Population studied

**Short description of the study population**

Pregnant women in EFEMERIS database who delivered between July 1, 2005 and December 31, 2012.

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## Age groups

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
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## Special population of interest

Pregnant women

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## Estimated number of subjects

70000

# Study design details

## Outcomes

prescription of asthma medication, pregnancy losses, birth defects, preterm births, low birth weight.

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## Data analysis plan

First, a description of prescription of asthma medications will be made. Second, we will compare pregnancy outcomes and newborn health between asthmatic and non-asthmatic women. We will use multiple logistic regression to analyze risks for each outcome associated with asthma, taking into potential confounders. Unadjusted and adjusted odds ratios will be presented.

# Documents

## Study publications

[Beau AB, Didier A, Hurault-Delarue C, Montastruc JL, Lacroix I, Damase-Michel C...](#)

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## Data management

ENCePP Cool

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 \(e.g., claims\)](#)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## 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