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

Study ID

17493

DARWIN EU® study

No

Study countries

☐ France

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.

Study status

Finalised

Research institutions and networks

Institutions

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

France

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Last updated: 01/07/2024

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

Contact details

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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

Study start date

Planned: 01/01/2015

Actual: 01/01/2015

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

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

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.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

70000

Study design details

Outcomes

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

Data analysis plan

First, a description of prescription of asthma medications wil 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. Unajusted and ajusted odds ratios will be presented.

Documents

Study publications

Beau AB, Didier A, Hurault-Delarue C, Montastruc JL, Lacroix I, Damase-Michel C...

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)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown