

# Pregnancy outcome in women exposed to dopamine agonists during pregnancy: a study in EFEMERIS database

**First published:** 05/12/2013

**Last updated:** 30/01/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5362

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### Study ID

16882

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

Data from EFEMERIS, a cohort of 57,408 pregnant women living in South West France were used to compare women exposed to dopamine agonists during pregnancy and unexposed women. The exposed group included women who received at least one prescription for one dopamine agonist during pregnancy. These women were individually matched with two unexposed women from the cohort for age and the month-and-year of the start of pregnancy. Pregnancy losses, birth defects, preterm births, low birth weight and psychomotor development were studied.

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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**

Actual: 01/02/2012

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### **Study start date**

Actual: 01/03/2012

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### **Data analysis start date**

Actual: 01/03/2012

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### **Date of final study report**

Actual: 01/07/2013

## 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 was to describe pregnancy outcomes in women exposed to prescription of dopamine agonists in EFEMERIS, and to compare with unexposed women.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

BROMOCRIPTINE

CABERGOLINE

LISURIDE

QUINAGOLIDE

APOMORPHINE

PERGOLIDE

PIRIBEDIL

PRAMIPEXOLE

ROPINIROLE

LEVODOPA

## Population studied

## **Short description of the study population**

Pregnant women in EFEMERIS database who were either exposed or unexposed to dopamine agonists and living in South West France.

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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**

549

# Study design details

## **Outcomes**

Pregnancy losses, birth defects, preterm births, low birth weight, psychomotor development.

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## **Data analysis plan**

Maternal characteristics and adverse fetal outcomes in the two groups ("exposed" and "unexposed") were described and compared by simple conditional logistic regression. Then, we used conditional logistic regression to analyze risks for each outcome associated with dispensation of dopamine agonists. To identify confounders, we used simple conditional logistic regression to evaluate the association between each potential confounder (dispensation of folic acid and progesterone during organogenesis, multiple births, preterm

birth, gender, mother's occupation, number of ultrasound scans during pregnancy, pathologies during pregnancy) and each outcome. For psychomotor development, the small sample sizes led us to use exact conditional logistic regression. For analysis of the risk of pregnancy loss, survival analysis was also used, as a sensitivity analysis, to take the time-dependant characteristics of exposure into account. Cox proportional hazard regression was applied.

## Documents

### Study publications

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

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## 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

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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