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

First published: 05/12/2013

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Study | Finalised

Administrative details

EU PAS number

EUPAS5362

Study ID

16882

DARWIN EU® study

No

Study countries

France

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.

Study status

Finalised

Research institutions and networks

Institutions

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

France

First published: 31/03/2022

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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

Actual: 01/02/2012

Study start date

Actual: 01/03/2012

Data analysis start date

Actual: 01/03/2012

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

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 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.

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

549

Study design details

Outcomes

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

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…

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