

EFEMERIS - Assessment of Prescribed Drugs and Associated Risk During Pregnancy

Head :Damase-Michel Christine, SERVICE DE PHARMACOLOGIE CLINIQUE UNITE « MEDICAMENTS, GROSSESSE ET ALLAITEMENT » UMR 1027, Equipe 6
Lacroix Isabelle, SERVICE DE PHARMACOLOGIE CLINIQUE UNITE « MEDICAMENTS, GROSSESSE ET ALLAITEMENT » UMR 1027

Last update : 10/29/2020 | Version : 3 | ID : 60124

General	
Identification	
Detailed name	Assessment of Prescribed Drugs and Associated Risk During Pregnancy
Sign or acronym	EFEMERIS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 05-1140 ; 07/04/2005
General Aspects	
Medical area	Gynecology/ obstetrics Pediatrics
Health determinants	Iatrogenic Medicine
Keywords	newborns, neonatal diseases, congenital anomalies, pregnancy, drugs, psychomotor development, pharmacology, abortions
Scientific investigator(s) (Contact)	
Name of the director	Damase-Michel
Surname	Christine
Address	31000 TOULOUSE
Email	medrepro@chu-toulouse.fr
Unit	SERVICE DE PHARMACOLOGIE CLINIQUE UNITE « MEDICAMENTS, GROSSESSE ET ALLAITEMENT » UMR 1027, Equipe 6

Organization	UNITE DE PHARMACOEPIDEMIOLOGIE : EVALUATION DE L'EXPOSITION ET DU RISQUE MEDICAMENTEUX
Name of the director	Lacroix
Surname	Isabelle
Address	31000 TOULOUSE
Email	medrepro@chu-toulouse.fr
Unit	SERVICE DE PHARMACOLOGIE CLINIQUE UNITE « MEDICAMENTS, GROSSESSE ET ALLAITEMENT » UMR 1027
Organization	UNITE DE PHARMACOEPIDEMIOLOGIE : EVALUATION DE L'EXPOSITION ET DU RISQUE MEDICAMENTEUX
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Public
Details	Agence nationale de sécurité du médicament et des produits de santé (ANSM - France)
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU Toulouse
Organisation status	Public
Presence of scientific or steering committees	No
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study

Database recruitment is carried out by an intermediary	A selection of health institutions and services An administrative base or a register
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	To form a cohort of pregnant women in monitoring the registration of medication prescribed and dispensed (during pregnancy) and the outcome of these pregnancies, so as to investigate the potential effects of exposure to drugs on newborns (prematurity, malformations, neonatal pathologies, psychomotor development).
Inclusion criteria	- Women with general state coverage administrated by the primary health insurance fund who gave birth in Haute-Garonne; - women who did not refuse access to information concerning them; - women who have at least one newborn health certificate registered at Mother and Child Protection level or whose pregnancy outcome has been identified by the University Hospital Center .
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	Departmental
French regions covered by the database	Languedoc-Roussillon Midi-Pyrénées
Detail of the geography area	Haute-Garonne
Data collection	
Dates	
Date of first collection (YYYY or	07/2004

MM/YYYY)

Date of last collection (YYYY or MM/YYYY) 2017

Size of the database

Size of the database (number of individuals) Greater than 20 000 individuals

Details of the number of individuals plus de 135,000

Data

Database activity Current data collection

Type of data collected Clinical data
Administrative data

Clinical data (detail) Medical registration

Presence of a biobank No

Health parameters studied Health event/morbidity
Health event/mortality
Health care consumption and services

Care consumption (detail) Hospitalization
Medicines consumption

Procedures

Participant monitoring Yes

Monitoring procedures Monitoring by crossing with a medical-administrative database

Details on monitoring of participants Duration 24 months

Links to administrative sources Yes

Linked administrative sources (detail) Cross-referencing 3 databases - Haute-Garonne CPAM (collection of medication prescribed during pregnancy), - PMI (collection of data for obligatory child health certificates at 8 days, 9 months and 24 months), - University Hospital Center (collection of data concerning pregnancy terminations).

Promotion and access

Promotion

Link to the document	http://www.efemeris.fr/communications.html
----------------------	---

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=EFEMERIS
----------------------	---

Description	List of publications in Pubmed
-------------	--------------------------------

Access

Presence of document that lists variables and coding procedures	Yes
---	-----

Terms of data access (charter for data provision, format of data, availability delay)	To be decided if data may be used by academic teams or by industrial teams.
---	---

Access to aggregated data	Access on specific project only
---------------------------	---------------------------------

Access to individual data	Access on specific project only
---------------------------	---------------------------------