

PELAGIE - Assessment of the Impact of Exposure to Occupational and Environmental Chemicals During Pregnancy on Pregnancy Outcome and Child Development

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General

Identification

Detailed name Assessment of the Impact of Exposure to Occupational and Environmental Chemicals During Pregnancy on Pregnancy Outcome and Child Development

Sign or acronym PELAGIE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL n°902076

General Aspects

Medical area Endocrinology and metabolism
Gynecology/ obstetrics
Pediatrics
Psychology and psychiatry

Study in connection with Covid-19 No

Health determinants Climate
Geography
Intoxication
Lifestyle and behavior
Occupation
Pollution

Keywords Solvents, Persistent Organic Pollutants, Water Disinfection by-products; Pregnancy outcomes, child development. Main cohort topics: Health and environment., Pesticides

Scientific investigator(s) (Contact)

Name of the director Chevrier

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Collaborations

Participation in projects, networks and consortia Yes

Details Europeans projects: Hi-WATE, ENRIECO, CHICOS,...

Funding

Funding status Public

Details InVS, direction des relations du travail (Ministère des affaires sociales), ANR, ANSES-AFFSET, Fondation de France, DRASS Bretagne.

Governance of the database

Sponsor(s) or organisation(s) responsible Institut National de la Santé et de la Recherche Médicale

Organisation status Public

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

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. Prospective Other bodies active in creating this cohort: CHU RENNES, maternity hospitals, obstetricians, paediatricians, biological laboratories in Lille and Brest. Pregnant women inclusion cut-off date: 01/12/2005

Database objective

Main objective

General objective: to assess the impact of early-life exposure to occupational and environmental chemicals on pregnancy outcome and child development, including exposure to solvents, pesticides, persistants pollutants and chlorinated derivatives in water.

Secondary objectives:

- to identify environmental sources and individual determinants (socio-demographic characteristics, lifestyle, genetic susceptibility) of exposure to pollutants measured by biomarkers
- to investigate the respective roles of prenatal exposure and exposure during childhood

Inclusion criteria

Women in their first trimester of pregnancy (less than 19 weeks amenorrhoea) living in one of the "départements" participating in the study.

Population type

Age

Newborns (birth to 28 days)
Early childhood (2 to 5 years)
Childhood (6 to 13 years)
Adolescence (13 to 18 years)
Adulthood (19 to 24 years)

Population covered

General population

Pathology

Gender

Male
Woman

Geography area

Regional

French regions covered by the database

Bretagne

Detail of the geography area

Multicentric cohort throughout France (40 centres):
ILLE ET VILAINE, COTES D'ARMOR, FINISTERE

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

03/2002

Date of last collection (YYYY or MM/YYYY)

on-going

Size of the database

Size of the database (number of individuals) [1000-10 000] individuals

Details of the number of individuals 3421

Data

Database activity Current data collection

Type of data collected
Clinical data
Declarative data
Paraclinical data
Biological data

Clinical data (detail)
Direct physical measures
Medical registration

Details of collected clinical data
At birth; neuropsychological examination at 6 years old; growth and pubertal development at 12 years old

Declarative data (detail)
Paper self-questionnaire

Biological data (detail)
Type of samples taken: umbilical cord blood, urine (prenatal, childhood), placenta fragment, hair (maternal at birth, childhood), saliva (mother, child), blood (child)

Presence of a biobank Yes

Contents of biobank
Whole blood
Serum
Cord blood
Fluids (saliva, urine, amniotic fluid, ?)
Tissues
DNA

Health parameters studied
Health event/morbidity
Health event/mortality

Procedures

Data collection method
Self-administered questionnaire: manual input with double data entry
Clinical examinations: manual input with double data entry

Participant monitoring Yes

Monitoring procedures
Monitoring by contact with the participant (mail, e-

mail, telephone etc.)

Details on monitoring of participants (Indefinite duration)

Links to administrative sources Yes

Linked administrative sources (detail) SISE-WATER

Promotion and access

Promotion

Link to the document <http://www.hal.inserm.fr/PELAGIE>

Description List of publications in HAL

Link to the document <http://tinyurl.com/Publications-Pubmed-PELAGIE>

Description List of publications in Pubmed

Access

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

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only