

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

Health determinants Climate
Geography
Intoxication
Lifestyle and behavior
Occupation
Pollution

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

Scientific investigator(s) (Contact)

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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, persistent 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)
Childhood (6 to 13 years)
Adolescence (13 to 18 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 | Data collection completed |
| Type of data collected | Clinical data Declarative 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 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