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

Head: Chevrier Cécile, IRSET U1085 INSERM Université Rennes 1

Last update: 09/05/2017 | Version: 3 | ID: 73143

## 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

## Collaborations

Yes

### Participation in projects, networks and consortia

Europeans projects: Hi-WATE, ENRIECO, CHICOS,...
Funding status
Public

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

Scientific investigator(s) (Contact)
Chevrier
Cécile

Phone
+33 (0)2 23 23 61 26

Email
cecile.chevrier@inserm.fr

Unit
IRSET U1085 INSERM Université Rennes 1

Additional contact

Main features

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.

Database objective
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
### 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

<table>
<thead>
<tr>
<th>Age</th>
<th>Population covered</th>
<th>Gender</th>
<th>Geography area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborns (birth to 28 days)</td>
<td>General population</td>
<td>Male</td>
<td>Regional</td>
</tr>
<tr>
<td>Childhood (6 to 13 years)</td>
<td></td>
<td>Woman</td>
<td>Bretagne</td>
</tr>
<tr>
<td>Adolescence (13 to 18 years)</td>
<td></td>
<td></td>
<td>Multicentric cohort throughout France (40 centres): ILLE ET VILAINE, COTES D'ARMOR, FINISTERE</td>
</tr>
</tbody>
</table>

### Data collection

<table>
<thead>
<tr>
<th>Dates</th>
<th>Size of the database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of first collection (YYYY or MM/YYYY)</td>
<td>[1000-10 000] individuals</td>
</tr>
<tr>
<td>Date of last collection (YYYY or MM/YYYY)</td>
<td>on-going</td>
</tr>
</tbody>
</table>

03/2002
<table>
<thead>
<tr>
<th>Details of the number of individuals</th>
<th>3421</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database activity</td>
<td>Data collection completed</td>
</tr>
</tbody>
</table>
| 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 | Self-administered questionnaire: manual input with double data entry  
Clinical examinations: manual input with double data entry |
| Data collection method | Yes |
| 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)

### Promotion and access

#### Promotion

<table>
<thead>
<tr>
<th>Link to the document</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.hal.inserm.fr/PELAGIE">http://www.hal.inserm.fr/PELAGIE</a></td>
<td>List of publications in HAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Link to the document</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://tinyurl.com/Publications-Pubmed-PELAGIE">http://tinyurl.com/Publications-Pubmed-PELAGIE</a></td>
<td>List of publications in Pubmed</td>
</tr>
</tbody>
</table>

#### Access

<table>
<thead>
<tr>
<th>Terms of data access (charter for data provision, format of data, availability delay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data may be used by academic teams To be decided if data may be used by industrial teams.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access to aggregated data</th>
<th>Access to individual data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access on specific project only</td>
<td>Access on specific project only</td>
</tr>
</tbody>
</table>