

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)	
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Collaborations

Participation in projects, networks and consortia	Yes
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Details	Europeans projects: Hi-WATE, ENRIECO, CHICOS,...
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Funding

Funding status	Public
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Details	InVS, direction des relations du travail (Ministère des affaires sociales), ANR, ANSES-AFFSET, Fondation de France, DRASS Bretagne.
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Governance of the database

Sponsor(s) or organisation(s) responsible	Institut National de la Santé et de la Recherche Médicale
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Organisation status	Public
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is carried out as part of an interventional study	No
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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
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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)
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Population covered	General population
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Pathology

Gender	Male Woman
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Geography area	Regional
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French regions covered by the database	Bretagne
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Detail of the geography area	Multicentric cohort throughout France (40 centres): ILLE ET VILAINE, COTES D'ARMOR, FINISTERE
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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)
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Links to administrative sources	Yes
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Linked administrative sources (detail)	SISE-WATER
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Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/PELAGIE
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Description	List of publications in HAL
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Link to the document	http://tinyurl.com/Publications-Pubmed-PELAGIE
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Description	List of publications in Pubmed
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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.
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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