

SEPAGES, Sépages - Monitoring of Exposure to Air Pollution during Pregnancy and Effect on Health

Head :Slama Rémy, IAB, Inserm, CNRS and University Grenoble-Alpes joint research center
Pin Isabelle, IAB, Inserm, CNRS and University Grenoble-Alpes joint research center

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General	
Identification	
Detailed name	Monitoring of Exposure to Air Pollution during Pregnancy and Effect on Health
Sign or acronym	SEPAGES, Sépages
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL agreement no. 912098, favourable opinion received on 04/10/2012
General Aspects	
Medical area	Endocrinology and metabolism Gynecology/ obstetrics Neurology Pediatrics Pneumology Study of allergies
Pathology (details)	Respiratory diseases
Health determinants	Climate Genetic Geography Lifestyle and behavior Nutrition Pollution Others (specify)
Others (details)	Endocrine disruptors
Keywords	atmospheric pollution, respiratory health, foetal growth, epigenetics, phenols, bisphenol A, Exposure, foetus, newborn, pregnancy, environment, child, phthalates, BPA
Scientific investigator(s) (Contact)	
Name of the director	Slama

Surname	Rémy
Address	Allée des Alpes, F-38700 La Tronche, France
Phone	+33 (0)4 76 54 94 02
Email	remy.slama@univ-grenoble-alpes.fr
Unit	IAB, Inserm, CNRS and University Grenoble-Alpes joint research center
Organization	Inserm - Institut national de la santé et de la recherche médicale
Name of the director	Pin
Surname	Isabelle
Address	Allée des Alpes, F-38700 La Tronche, France
Email	ipin@chu-grenoble.fr
Unit	IAB, Inserm, CNRS and University Grenoble-Alpes joint research center
Organization	Inserm et CHU de Grenoble
Collaborations	
Participation in projects, networks and consortia	Yes
Details	European Helix project
Others	HBM4EU
Funding	
Funding status	Public
Details	- European Research Council - ANR
Governance of the database	
Sponsor(s) or organisation(s) responsible	Inserm - Institut national de la santé et de la recherche médicale
Organisation status	Public
Presence of scientific or steering committees	Yes

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.	Couples-children cohort. Participation on a voluntary basis, inclusion is in the first trimester of pregnancy (or early in the second trimester).
Database objective	
Main objective	<p>The main objectives are:</p> <ul style="list-style-type: none"> - to better characterise environmental exposure experienced during pregnancy and its impact on the health of a pregnant woman, foetus, newborn and child by paying particular attention to foetal growth and respiratory health - to study the biological mechanisms by which environmental factors might influence health, particularly epigenetic mechanisms. <p>The targeted environmental factors are:</p> <ul style="list-style-type: none"> - air pollutants (fine particles, nitrogen oxide, benzene and BTEX series) - endocrine disruptors, including phenols and phthalates - at term, exposome
Inclusion criteria	<ul style="list-style-type: none"> - be aged over 18 years - be covered by a social security system (French or foreign) - be pregnant by 19 weeks and 6 days maximum - have a single pregnancy (and not twins) - reside in Isère, in an area not more than one hour from Grenoble - not be considering moving away from the inclusion area within the next two years
Population type	

Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	Local
French regions covered by the database	Auvergne Rhône-Alpes
Detail of the geography area	Grenoble urban area (4 maternity clinics of Grenoble: Clinique Belledonne, Clinique des Cèdres, Clinique du Groupe Hospitalier Mutualiste or at the Hôpital Couple Enfant)
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	03/2014
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	500 families (mother, father, child) (estimation)
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Clinical data on the growth, respiratory and cardiovascular health of the parents in the first stage and then that of their child from birth.

Declarative data (detail)	Internet self-questionnaire
Details of collected declarative data	Questionnaires, (self)-administered via a computer platform, to better understand the environment in which the volunteers live (Environmental exposure in the workplace, the presence of domestic animals at home, tobacco consumption, dietary habits, etc.).
Paraclinical data (detail)	Individual measurement tools (GPS, accelerometers, atmospheric pollution dosimeters).
Biological data (detail)	During pregnancy: urine, blood and hair specimens. At the time of delivery: placenta, tissue, blood, urine, hair, meconium and milk specimens.
Presence of a biobank	Yes
Contents of biobank	DNAC/RNAm
Details of biobank content	The RNA and DNA are stored in numbered tubes with no nominal information.
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Other (detail)	Exposure to atmospheric pollution; exposure to endocrine disruptors (phenols, phthalates)
Procedures	
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by convocation of the participant
Details on monitoring of participants	The monitoring of the pregnancy takes place until the birth of the child then the monitoring of the child continues until at least 3 years of age.
Followed pathology	J00-J06 - Acute upper respiratory infections
	J20-J22 - Other acute lower respiratory infections
	J30-J39 - Other diseases of upper respiratory tract

J40-J47 - Chronic lower respiratory diseases

J45 - Asthma

E65-E68 - Obesity and other hyperalimentation

F54 - Psychological and behavioural factors associated with disorders or diseases classified elsewhere

Links to administrative sources No

Promotion and access

Promotion

Access

Dedicated website <http://sepages.inserm.fr/fr/accueil/>

Presence of document that lists variables and coding procedures No

Terms of data access (charter for data provision, format of data, availability delay) Contact the scientist in charge.

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only