EDEN - Study on the pre and early postnatal determinants of child health and development

Head :Heude Barbara, U1018 CENTRE DE RECHERCHE EN ÉPIDÉMIOLOGIE ET SANTÉ DES POPULATIONS Charles Marie-Aline, U1018 CENTRE DE RECHERCHE EN ÉPIDÉMIOLOGIE ET SANTÉ DES POPULATIONS

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General	
Identification	
Detailed name	Study on the pre and early postnatal determinants of child health and development
Sign or acronym	EDEN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°902267 (2002), CPP 0270 (12/12/2002)
General Aspects	
Medical area	Endocrinology and metabolism Study of allergies
Health determinants	Addictions Climate Genetic Geography Nutrition Occupation Pollution Social and psychosocial factors
Keywords	Health outcome, male reproductive system, metabolism, motor and cognitive development, growth, adiposity, infections, blood pressure, environment
Scientific investigator(s) (Contact)	
Name of the director	Heude
Surname	Barbara
Phone	+33 (0)1 45 59 51 85
Email	barbara.heude@inserm.fr

Unit	U1018 CENTRE DE RECHERCHE EN ÉPIDÉMIOLOGIE ET SANTÉ DES POPULATIONS
Organization	Inserm
Name of the director	Charles
Surname	Marie-Aline
Phone	+33 (0)1 45 59 51 05
Email	marie-aline.charles@inserm.fr
Unit	U1018 CENTRE DE RECHERCHE EN ÉPIDÉMIOLOGIE ET SANTÉ DES POPULATIONS
Organization	Inserm
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Mixed
Details	Fondation pour la recherche médicale, Inserm, Ministère de la recherche, Université Paris Sud, ANR, AFSSET, DGS, InVS, Nestlé, INPES, DGS, ALFEDIAM, Société SAVANTE, MGEN, IReSP, Commission européenne
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 No out as part of an interventional study

Additional information regarding Prospective follow-up until 8 years sample selection.

Database objective	
Main objective	Examine relationships between on the one hand, exposition and pregnancy related health factors, in utero fetal development, newborn health and child health during first months of life, and on the other hand, later child health and development
Inclusion criteria	Adult women (?18years) presenting before 22 gestational age at first prenatal visit, able to speak and read french
Population type	
Age	Newborns (birth to 28 days) Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population covered	General population
Gender	Woman
Geography area	Local
French regions covered by the database	Alsace Champagne-Ardenne Lorraine Aquitaine Limousin Poitou-Charentes
Detail of the geography area	French multicentric cohort; 2 centres: Nancy and Poitiers
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/2003
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2002 femmes/women, 1898 nouveau- nés/newborns

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 examination during pregnancy and at birth for the mother and at birth, 1, 3 and 5 years for the offspring. Collected information concerning mother: medical records, post partum period, ultrasound data; and concerning the offspring: growth, adiposity, bone development, cognitive development, blood pressure, heart rate, dental examination, spirometry (5 years)
Declarative data (detail)	Face to face interview
Details of collected declarative data	Clinical examination during pregnancy and at birth for the mother and at birth, 1, 3 and 5 years for the offspring. Collected information concerning mother: medical records, post partum period, ultrasound data; and concerning the offspring: growth, adiposity, bone development, cognitive development, blood pressure, heart rate, dental examination, spirometry (5 years)
Paraclinical data (detail)	Ultrasound
Biological data (detail)	ciological samples: maternal and paternal blood; placenta; maternal hair and urine; colostrum in breastfeeding mothers; cord blood; child meconium and hair at birth; child blood and urine at 5 years
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Cord blood Fluids (saliva, urine, amniotic fluid, ?) DNA
Details of biobank content	urine, colostrum, hair, placenta pieces
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	auto-questionnaire: manual entering from paper questionnaireclinical examinations: direct enteringbiological data: manual entering
Participant monitoring	Yes
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/EDEN
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-EDEN
Description	List of publications in Pubmed
Access	
Dedicated website	https://eden.vjf.inserm.fr/
Terms of data access (charter for data provision, format of data, availability delay)	Possible use of data by academic teams. Possible use of data by industry
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only