EPIPAGE 2 - Epidemiological study on low gestational age infants 2

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General

Identification

Detailed name	Epidemiological study on low gestational age infants 2
Sign or acronym	EPIPAGE 2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°911009 / CCTIRS n°10.626 / CPP SC-2873

General Aspects

Medical area	Gynecology/ obstetrics Pediatrics
Health determinants	Genetic
Keywords	Perinatality, neonatal mortality and morbidity (respiratory, neurological, infectious, metabolic), neural development (motor, sensory, cognitive), growth), handicaps

Scientific investigator(s) (Contact)

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	enfants
Organization	INSERM

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Mixed
Details	Ce projet a été financé grâce au soutien de:1) l'Institut de Recherche en Santé Publique / Institut Thématique Santé Publique, et des partenaires financeurs suivants : Ministère de la santé et des sports, Ministère délégué à la recherche, Institut National de la Santé et de la Recherche Médicale, Institut National du Cancer et Caisse Nationale de solidarité pour l'Autonomie.2) la fondation PREMUP3) Programme EQUIPEX des Investissements d'avenir dans le cadre de la plateforme RE-CO-NAI

Governance of the database

Sponsor(s) or organisation(s) responsible	Institut National de la Santé et de la Recherche Médicale - INSERM
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. End of inclusions: 01/12/2011

Database objective

Main objective	More than 10 years are passed since the beginning of the EPIPAGE study. The evolutions occurred since justify the creation of a new cohort. The main objectives of EPIPAGE 2 are: 1) Study the becoming of extremely premature children and their families 2) The evaluation of care organization effects and medical practice on premature children's health and development 3) Research of causes and consequences of prematurity 4) Study the path of the different families and the decisions process at the moment of birth and intensive care 5) The needs analysis of medical and educational care One of the originalities of the study is to have permitted the creation of complementary and multidisciplinary projects, in order to reply and deepen to question difficult to handle on the children of the cohort. These projects, based on the same structure of EPIPAGE 2, needs additional investigations and an own funding. A total of 8 studies have been developed in the field of brain imaging, bio-markers, nutrition, mother-child interaction and ethics: - ETHIQUE (decision process leading to survival or death of children born between 22 and 26 weeks of amenorrhea) - EPIFLORE (study of the introduction of the intestinal microbiota) - EPIRMEX (Study of the executive functions and of the language development, depending on anomalies detected through NRM) - BIOPAG (Identification of the early bio-markers of pathologies from an umbilical cord sample (DNA, RNA) - OLIMPE (Study of the existing links between the quality of early mother-child interactions and the neural and developmental becoming) - CHORHIST (Research of chorioamniontides through anatomo-pathological analysis of placenta) - EPINUTRI (Study of the associations of the intake of polyunsaturated fatty acids, iron intake and neurological becoming of extremely premature children) - EPIPAIN 2 (treatment of painful movements in

	neonatal intensive care. RE-CO-NAI platform EPIPAGE 2 is one of the two cohorts constituting the RE-CO-NAI platform, together with the ELFE cohort. The general objective of this platform is to create an infrastructure offering the measures required for collecting, highly secured storage and distribution of data concerning the pregnancy, the birth and the child. The research platform consist of cohorts of infants followed since birth will allow to study, in a global and multidisciplinary way, the stakes on health, development and socialization of children. It will in addition provide substantial visibility in the world of academic research (French and international), but also with regards to bodies, associations, and industries that have interests in children. As such, it will allow for an optimized valorization of the data collected and will facilitate the dissemination of data.
Inclusion criteria	EPIPAGE 2 is a population based perspective cohort. All the children born in 25 regions of France, extremely premature (22-26 weeks of amenorrhea) on 8 months, highly premature (27-31 weeks of amenorrhea) on 6 months and moderately premature (32-34 weeks of amenorrhea) on 1 month. A control group of full-born children will be constituted from Elfe study. Children of families having expressed a refusal will not be included. In this case, the information from the health certificate of the 8th day could be used to characterize the population concerned.
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years)
Population covered	General population
Gender	Male Woman
Geography area	National
Detail of the geography area	21 regions of metropolitan France and 4 overseas regions (Martinique, Guadeloupe, Guyana, Réunion)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	04/2011

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	- 8398 prématurés/premature births and Induced therapeutic abortions/avortements - 7595 enfants/children

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at inclusion and during the follow-up (birth, 2 years, 5years, 8 years, 11-12 years). Information collected through the clinical examination: motor, sensory, cognitive development, height and weight growth, respiratory pathologies
Declarative data (detail)	Paper self-questionnaire Face to face interview
Details of collected declarative data	Clinical examination at inclusion and during the follow-up (birth, 2 years, 5years, 8 years, 11-12 years). Information collected through the clinical examination: motor, sensory, cognitive development, height and weight growth, respiratory pathologies
Biological data (detail)	Biological data from coming from the medical record. For a sub-sample of children (n=150), umbilical cord blood has been taken
Presence of a biobank	Yes
Contents of biobank	Whole blood Cord blood Fluids (saliva, urine, amniotic fluid, ?)

	Tissues Others
Details of biobank content	Maternal blood, umbilical cord blood, stools of the newborn. The constitution of the biological collections that will allow a number of early exposures, as well as markers of health condition, is one of the specific objectives of the two studies of the RE-CO-NAI platform.
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception

Procedures

Data collection method	At birth (inclusion), clinical data are collected from the medical record and the medical teams, as well as information from the mother about pregnancy, delivery, intensive care (self-questionnaire and interview with the mother). During the follow-up, data are collected at 2, 5, 8 and 12 years. -A clinical and psychological check-up will be realized at 5, 8 and 12 years (motor, sensory, cognitive development, height and weight growth, respiratory pathologies) - Data concerning child's health, his development, his schooling, his quality of life, possible handicaps, consequences on the family are collected through a self-questionnaire submitted to the mother at 1, 2, 5, 8 and 12 years.
Quality procedure(s) used	Coherence request during and after computer data entry. Missing data checked back to the original file. Subjects an doctors remainders for follow-up visits. Internal quality audit report. Patients receive information about the use of their data.
Participant monitoring	Yes
Details on monitoring of participants	Children will be followed until 12 years old.
Links to administrative sources	Yes
Linked administrative sources (detail)	SNIIRAM (file under preparation)

Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/EPIPAGE

Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=epipage+OR+25541510[uid]+OR+19932945[uid]
Description	List of publications in Pubmed

Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data utilization possible for academic teams. Access to every interested research team after an evaluation of the project by the scientific council
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only