EPIPAGE 2 - Epidemiological study on low gestational age infants 2

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Général

Identification

Nom détaillé	Epidemiological study on low gestational age infants 2
Sigle ou acronyme	EPIPAGE 2
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CNIL n°911009 / CCTIRS n°10.626 / CPP SC-2873

Thématiques générales

Domaine médical	Gynecology/ obstetrics Pediatrics
Déterminants de santé	Genetic
Mots-clés	Perinatality, neonatal mortality and morbidity (respiratory, neurological, infectious, metabolic), neural development (motor, sensory, cognitive), growth), handicaps

Responsable(s) scientifique(s)

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Organisme	INSERM

Collaborations

Participation à des projets, des réseaux, des consortiums	Yes

Financements

Financements	Mixed
Précisions	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

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	Institut National de la Santé et de la Recherche Médicale - INSERM
Statut de l'organisation	Secteur Public

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Cohort study
Origine du recrutement des participants	A selection of health institutions and services
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	Prospective. End of inclusions: 01/12/2011

Objectif de la base de données

Objectif principal	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.
Critères d'inclusion	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.

Type de population

Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years)
Population concernée	General population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	21 regions of metropolitan France and 4 overseas regions (Martinique, Guadeloupe, Guyana, Réunion)

Collecte

Dates

Année du premier recueil	04/2011

Taille de la base de données

Taille de la base de données (en nombre d'individus)	[1000-10 000[individuals
Détail du nombre d'individus	- 8398 prématurés/premature births and Induced therapeutic abortions/avortements - 7595 enfants/children

Données

Activité de la base	Current data collection
Type de données recueillies	Clinical data Declarative data Biological data
Données cliniques, précisions	Direct physical measures Medical registration
Détail des données cliniques recueillies	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
Données déclaratives, précisions	Paper self-questionnaire Face to face interview
Détail des données déclaratives recueillies	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
Données biologiques, précisions	Biological data from coming from the medical record. For a sub-sample of children (n=150), umbilical cord blood has been taken
Existence d'une biothèque	Yes
Contenu de la biothèque	Whole blood Cord blood Fluids (saliva, urine, amniotic fluid, ?) Tissues

	Others
Détail des éléments conservés	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.
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Quality of life/health perception

Modalités

Mode de recueil des données	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.
Procédures qualité utilisées	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.
Suivi des participants	Yes
Détail du suivi	Children will be followed until 12 years old.
Appariement avec des sources administratives	Yes
Sources administratives appariées, précisions	SNIIRAM (file under preparation)

Valorisation et accès

Valorisation et accès

Lien vers le document	http://www.hal.inserm.fr/EPIPAGE
Description	List of publications in HAL

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

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Data utilization possible for academic teams. Access to every interested research team after an evaluation of the project by the scientific council
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only