

EPICARD - Future development of children suffering from congenital heart diseases : a study in Ile de France

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General

Identification

Detailed name	Future development of children suffering from congenital heart diseases : a study in Ile de France
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Sign or acronym	EPICARD
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL No. 903006, CPP 2013-A00234-14, ANSM 130214B-21
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General Aspects

Medical area	Pediatrics
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Health determinants	Genetic
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Keywords	Prenatal diagnosis, perinatal medicine, pediatrics, mortality, morbidity, development, KABC
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Scientific investigator(s) (Contact)

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ENFANTS

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Organization	INSERM
Collaborations	
Funding	
Funding status	Mixed
Details	- PHRC national - Association AREMCAR - ITMO- Santé Publique - Abbvie (projet PULMOCARD)
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 as part of an interventional study	No
Additional information regarding sample selection.	Cases identification: - For cases diagnosed during pregnancy or at born: obstetrics and gynecology departments, multidisciplinary intensive care and departments, neonatology departments, pediatric mobile emergency and intensive care services, DFPE (health certificates) - For diagnosis after maternity ward: from pediatric cardiology departments, and the following centers: fetal echocardiology centers, neonatology and multidisciplinary intensive care departments, pediatric mobile emergency and intensive care service, DFPE - For children dead before all kind of heart disease diagnosis: pediatric mobile emergency and intensive care service, fetopathology and anatomopathology services and sudden death centers. The Arcs research cases in the centers participating with a different frequency, depending on expected cases.
Database objective	
Main objective	The objectives of the study are, from a cohort survey on a population of patients suffering from congenital heart diseases: 1) estimate the prevalence, the time of diagnosis, the medical and surgical care of congenital heart diseases infected newborns 2) Evaluate the mortality, the morbidity and future neural development of these children 3) Identify factors linked to short and long term prognosis, including the impact of the time of diagnosis, medical and surgical care of the children, as well as the role of the channels of health care, and socio-economic factors.
Inclusion criteria	Children (or fetus) suffering from congenital heart diseases detected in prenatal screening, at birth or

during the first year of life, born (or interrupted)
between 2005 and 2008, from mothers residents in
Paris or inner suburbs (92, 93, 94 departments)

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)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	Departmental
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French regions covered by the database	Île-de-France
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Detail of the geography area	Paris, innersuburbs (92, 93, 94)
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	05/2005
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Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
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Details of the number of individuals	2348
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Declarative data
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Clinical data (detail)	Medical registration
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Declarative data (detail)	Paper self-questionnaire Face to face interview
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Others
Care consumption (detail)	Hospitalization Medicines consumption
Other (detail)	Future neural development of the child
Procedures	
Data collection method	Data have been collected by the investigators from medical records of the centers participating to the study. Pediatricians filling the questionnaires (pediatric cardiology: diagnostic), at 1 year, and at 31/2 years and 8 years. Standardized neural development tests -K-ABC and NEPSY.
Participant monitoring	Yes
Details on monitoring of participants	Systematic review at 1 year of all the children and at 31/2 years for some of them (1165 children with a major congenital heart disease and a random sample (~15%) of children with a minor CIV/CIA) by a pediatrician. Follow up by mail for families who wasn't able to move.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/EPICARD
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-EPICARD
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Access to data with the accord fo the steering committee, priority to study participants
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only