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

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## General

### Identification

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| Detailed name | Future development of children suffering from congenital heart diseases : a study in Ile de France |
| Sign or acronym | EPICARD |
| 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 |

### General Aspects

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| Medical area | Pediatrics |
| Health determinants | Genetic |
| Keywords | Prenatal diagnosis, perinatal medicine, pediatrics, mortality, morbidity, development, KABC |

### Scientific investigator(s) (Contact)

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## Collaborations

## Funding

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| Funding status | Mixed |
| Details | - PHRC national - Association AREMCAR - ITMO-Santé Publique - Abbvie (projet PULMOCARD) |

## Governance of the database

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| Sponsor(s) or organisation(s) responsible | Institut national de la santé et de la recherche médicale (INSERM) |

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| Organisation status | Public |

## Additional contact

## Main features

## Type of database

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| 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

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| Main objective | The objectives of the study are, from a cohort survey on a population of patients suffering from congenital heart diseases:<br>1) estimate the prevalence, the time of diagnosis, the medical and surgical care of congenital heart diseases infected newborns<br>2) Evaluate the mortality, the morbidity and future neural development of these children<br>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 |

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| | 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

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| Age | Newborns (birth to 28 days)<br>Infant (28 days to 2 years)<br>Early childhood (2 to 5 years)<br>Childhood (6 to 13 years) |
| Population covered | Sick population |
| Gender | Male<br>Woman |
| Geography area | Departmental |
| French regions covered by the database | Île-de-France |
| Detail of the geography area | Paris, innersuburbs (92, 93, 94) |

## Data collection

### Dates

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| Date of first collection (YYYY or MM/YYYY) | 05/2005 |

### Size of the database

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

### Data

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| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data |
| Clinical data (detail) | Medical registration |
| Declarative data (detail) | Paper self-questionnaire<br>Face to face interview |
| Presence of a biobank | No |

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| Health parameters studied | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services<br>Others |
| Care consumption (detail) | Hospitalization<br>Medicines consumption |
| Other (detail) | Future neural development of the child |

## Procedures

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| 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

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| 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

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| 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 |