**General**

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

**Medical area**

- Pediatrics

**Health determinants**

- Genetic

**Keywords**

- Prenatal diagnosis, perinatal medicine, pediatrics, mortality, morbidity, development, KABC

**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
<table>
<thead>
<tr>
<th>Name of the director</th>
<th>Babak</th>
</tr>
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<tbody>
<tr>
<td>Surname</td>
<td>Khoshnood</td>
</tr>
<tr>
<td>Address</td>
<td>INSERM U953 Maternité de Port-Royal, 6ème étage 53 av. de l'Observatoire 75014 PARIS</td>
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<tr>
<td>Phone</td>
<td>+33 (0)1 42 34 55 87</td>
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<td>Email</td>
<td><a href="mailto:babak.khoshnood@inserm.fr">babak.khoshnood@inserm.fr</a></td>
</tr>
<tr>
<td>Unit</td>
<td>U953 - RECHERCHE EPIDEMIOLOGIQUE EN SANTE PERINATALE ET SANTE DES FEMMES ET DES ENFANTS</td>
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<th>Nathalie</th>
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<tr>
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<tr>
<td>Email</td>
<td><a href="mailto:nathalie.lelong@inserm.fr">nathalie.lelong@inserm.fr</a></td>
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</tbody>
</table>
**Type of database**

**Study databases**

**Cohort study**

**No**

**Database recruitment is carried out as part of an interventional study**

**Additional information regarding sample selection.**

**Cases identification:**
- For cases diagnosed during pregnancy or at birth: 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

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

Newborns (birth to 28 days)
Infant (28 days to 2 years)
Early childhood (2 to 5 years)
Childhood (6 to 13 years)

Population covered

Sick population

Gender

Male
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

Date of first collection (YYYY or MM/YYYY)

05/2005

Size of the database

Size of the database (number of individuals)

[1000-10 000] individuals

Details of the number of individuals

2348

Data

Database activity

Current data collection

Type of data collected

Clinical data
Declarative data

Clinical data (detail)

Medical registration

Declarative data (detail)

Paper self-questionnaire
Face to face interview
<table>
<thead>
<tr>
<th>Presence of a biobank</th>
<th>No</th>
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</table>
| 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 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. |
| Data collection method | 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 | Promotion and access | No |
| Promotion | Promotion  
Link to the document  
Description  
Link to the document  
Description  
Access  
Terms of data access (charter for data provision, format of data, availability delay)  
Access to aggregated data | |
| Link to the document | http://www.hal.inserm.fr/EPICARD  
List of publications in HAL  
http://tinyurl.com/Pubmed-EPICARD  
List of publications in Pubmed  
Access to data with the accord fo the steering committee, priority to study participants  
Access on specific project only |
Access to individual data

Access on specific project only