

COCCINELLE - Cohorte sur le risque de cancer après cardiologie interventionnelle pédiatrique

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General

Identification

Detailed name Cohorte sur le risque de cancer après cardiologie interventionnelle pédiatrique

Sign or acronym COCCINELLE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation autorisation CNIL n°911112, Décembre 2011

General Aspects

Medical area Cancer research
Cardiology

Keywords ionizing radiation, interventional cardiology, cancer, children

Scientific investigator(s) (Contact)

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Organization	IRSN

Collaborations
Funding

Funding status	Public
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Details	IRSN, INCa
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Governance of the database

Sponsor(s) or organisation(s) responsible	IRSN (Institut de radioprotection et de sûreté nucléaire)
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
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Database recruitment is made on the basis of:	Another treatment or procedure
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Database recruitment is carried out as part of an interventional study	No
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Database objective

Main objective	Children with congenital heart disease frequently undergo cardiac catheterization procedures for diagnostic or treatment purposes. Despite the clear clinical benefit to the patient, the complexity of these procedures may result in high cumulative radiation exposure. Given children's greater sensitivity to radiation and the longer life span during which radiation health effects can develop, an epidemiological cohort study, named Coccinelle (Cohorte sur le risque de cancer après cardiologie interventionnelle pédiatrique) is being launched in France to evaluate the risks of leukaemia and solid cancers in this specific population.
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Inclusion criteria	The study population will include all children who have undergone at least one cardiac catheterization procedure since 2000 and were under 10 years old and permanent residents of France at the time of the procedure. Electronically stored patient records from the departments of paediatric cardiology of the French national network for complex congenital heart diseases (M3C) are being searched to identify the children to be included.
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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) Adolescence (13 to 18 years)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	The minimum dataset will comprise: identification of
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the subject, characteristics of the procedure and technical details, such as fluoroscopy time and dose area product (DAP), which are needed to reconstruct the doses received by each child. The cohort will be followed up through linkage with the two French paediatric cancer registries, which record all cases of childhood leukaemia and solid cancers in France. Radiation exposure will be estimated retrospectively for each child included in the cohort. Organ doses, especially to the lung, the oesophagus, and the thyroid will then be calculated with PCXMC software.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 01/2011

Date of last collection (YYYY or MM/YYYY) 12/2014

Size of the database

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

Details of the number of individuals 8000

Data

Database activity Current data collection

Type of data collected
Clinical data
Paraclinical data
Administrative data

Clinical data (detail) Direct physical measures

Paraclinical data (detail) clinical data

Administrative data (detail) administrative data

Presence of a biobank No

Health parameters studied
Health event/morbidity
Health event/mortality

Procedures

Participant monitoring Yes

Links to administrative sources	Yes
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=%28%28Baysson[Author]+OR+Bernier[Author]+OR+Laurier[Author]%29+AND+%28coccinelle+OR+ladybird%29%29+OR+23521893[uid]
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	none
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only