TOMENF - Iatrogenic risks associated with CT scans received in childhood

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General

Identification

Detailed name	Iatrogenic risks associated with CT scans received in childhood
Sign or acronym	TOMENF
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 10/11/2009, number 1347141), CCTIRS (or French IRB) (l11/06/2009, number 09.271).

General Aspects

Medical area	Cancer research Radiology and medical imaging
Health determinants	Iatrogenic
Others (details)	all types of cancer and other radiation-induced diseases
Keywords	CT scan, medical exposure, iatrogenic effects of radiation, low doses of ionizing radiation, cerebrovascular disease, dosimetry, childhood, risk factors, cohort, cardiovascular disease

Scientific investigator(s) (Contact)

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Organization	INSERM - Institut National de la Santé et de la Recherche
Collaborations	
Funding	
Funding status	Mixed
Details	INSERM, European Commission (FP7-EURATOM-FISSION), Electricity of France (EDF)
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
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
Database recruitment is is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	This cohort study is based on data collection within French radiology departments. Cases are recorded in selected centers in France, according to the following criteria: radiology services with computerized medical records and with a significant activity in paediatrics (about a dozen center). Currently available data indicate that the total number of inclusion should be between 20 and 30,000.
Database objective	

Main objective	The main objective is to identify group of children who received CT scan and to study the long-term effects of the radiation in order to gain knowledge about all potential iatrogenic effects after exposure to CT scan in childhood by means of a cohort study. The study aims to: - identify a potential risk of radiation-induced cancer after CT scan in childhood, and quantify if any; - identify the factors affecting this potential risk, namely, the relationship with the dose received by the organ, the percentage of the irradiated body, age at CT scan, gender and possibly other carcinogenic factors. Secondary objectives are to identify potential risks of other radiation-induced diseases such as cerebrovascular and cardiovascular diseases and quantify them if they exist.
Inclusion criteria	- Child under 15 years at the CT scan - CT scan received for reasons other than suspicion of tumor - CT scan in the period 1998-2008 - Children whose main residence is in France at the time of CT scan

Population type

Age	Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	General population
Gender	Male Woman
Geography area	National
Detail of the geography area	France (French centers of radiology with computerized medical records)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009

Size of the database

Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	11 000
Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Paraclinical data (detail)	CT scan images and related computed tomography (date, pattern, underlying pathology, viewing area, availability of protocol, contrast, dose delivered, file dicom image scanners feature data protocols examinations).
Administrative data (detail)	Vital status and cause of death, cancer cases
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	The cohort consists of consultation of the radiology centers participating computerized medical records. Identification and anthropometric data, the pattern of the CT scan and dosimetric data are collected to estimate the CT dose. These data are then interconnected with consultation and cross medico-administrative databases providing information on vital status, causes of deaths and cancers. The methodology used is that of a retrospective cohort study with prospective follow-up.
Participant monitoring	Yes
Links to administrative sources	Yes
Linked administrative sources (detail)	The vital status, causes of deaths and cancer cases are updated every five years. The introduction of another form of monitoring, such as the use of the medical facilities of the French Health Insurance Information System will soon considered because it

	is essential to extend the monitoring of these children into adulthood. Follow-up with no end time.
Promotion and access	
Promotion **Access**	
Terms of data access (charter for data provision, format of data, availability delay)	This study is the French part of an international study (CHILD-MED-RAD: Cohort studies of children with substantial businesses diagnostic medical exposures). The International Agency for Research on Cancer (IARC) of the WHO (Lyon) has access to non-personal data. Terms of access to all or part of the data base is being set for outside teams who wish to study from these data.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only