

TOMENF2 - Cohort on Iatrogenic Risks Associated with CT Scans Received in Childhood

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General	
Identification	
Detailed name	Cohort on Iatrogenic Risks Associated with CT Scans Received in Childhood
Sign or acronym	TOMENF2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL n°1347141
General Aspects	
Medical area	Cancer research Cardiology Neurology Ophthalmology Radiology and medical imaging
Health determinants	Iatrogenic
Others (details)	Cancer, cardiovascular and cerebrovascular disease, cataracts
Keywords	Tomography, dose-effect relationship, CT scan, ionising radiation, iatrogenic effects, dosimetry
Scientific investigator(s) (Contact)	
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Organization	INSERM
Collaborations	
Funding	
Funding status	Mixed
Details	- INSERM - Commission Européenne - EDF Recherche de financements additionnels
Governance of the database	
Sponsor(s) or organisation(s) responsible	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 by an intermediary	A selection of health institutions and services
Database recruitment 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.	Only University Hospitals Centres with computerised data will be considered. Subjects admitted to one of these centres and meeting the required inclusion criteria were selected.
Database objective	
Main objective	The objective is to form a multicentric cohort of 30,000 children admitted to radiology departments in France in order to describe the pattern of computerised tomography use during childhood and to estimate the dosage associated with these examinations. This cohort will later explore the iatrogenic effects of low-dosage of ionising

radiation, carcinogenic and non-carcinogenic effects.

Inclusion criteria

- Children under 15 years old admitted to radiology services for initial examination after 1st January 2000 - Children permanently living in France - not diagnosed with cancer during first year after computerised tomography (CT) scan.

Population type

Age

Early childhood (2 to 5 years)
Childhood (6 to 13 years)
Adolescence (13 to 18 years)
Adulthood (19 to 24 years)

Population covered

General population

Gender

Male
Woman

Geography area

National

Detail of the geography area

University hospitals in Lyon, Caen and Reims at present. University hospitals in Brest, Rennes, Besançon, Amiens and Dijon pending agreement

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

30 000

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)	Personal information: name, gender, place of birth, date of birth, post code.
Administrative data (detail)	INSEE, SNIIRAM
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	The cohort will be prospectively monitored for cancers (leukaemias and solid tumours) as well as heart disease, cerebrovascular disease and cataracts by cross-referencing data from the National Registry of Solid Tumours and SNIIRAM. The acquisition of vital status and date of death from INSEE data, as well as cause of death will be carried out at the time the cohort is formed and every 5 years.
Links to administrative sources	Yes
Linked administrative sources (detail)	INSEE, SNIIRAM
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/24670918
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/24419490
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientific director.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only