FCCSS - Study on Long-Term Outcome for Subjects Cured of Childhood Cancer and Adolescents Diagnosed Before 2000 in France

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General

Identification

Detailed name	Study on Long-Term Outcome for Subjects Cured of Childhood Cancer and Adolescents Diagnosed Before 2000 in France
Sign or acronym	FCCSS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Registration no. (CNIL, CPP, CCTIRS etc.).

General Aspects

Medical area	Cancer research Cardiology Endocrinology and metabolism Neurology Nuclear medicine Odontology Ophthalmology Psychology and psychiatry Radiology and medical imaging
Health determinants	Addictions Genetic Iatrogenic Occupation Social and psychosocial factors
Keywords	iatrogenic effects, social integration, radiology, radiotherapy, chemotherapy, quality of life, France, mortality, cohort, solid cancer in childhood and adolescence, subsequent cerebrovascular and cardiovascular diseases, survivors, risk factors of iatrogenic pathologies, dosimetric reconstruction, second cancer

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	The project was funded by the Wyeth Foundation (now Pfizer foundation), the Force Foundation, the French National Cancer League (LNCC), the Hospital Clinical Research Programme (PHRC), French National Cancer Institute (INCa), Electricité de France (EDF), Gustave-Roussy and the French National Institute of Health and Medical Research (INSERM). FCCSS is currently funded by the PHRC, INSERM and the European Commission Seventh Framework Programme (7e PC) (PanCareSurFup, ProCardio and CerebRad projects). FCCSS is part of the HOPE-EPI project and is also financed by the French National Research Agency (ANR) and IReSP (Future Investments).

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 carried out as part of an interventional study	No
Additional information regarding sample selection.	The retrospective cohort was formed 1985 from medical records and archived radiotherapy data. The comprehensive collection outlined chemotherapy treatment characteristics and an estimate of ionising radiation dosage for cancer treatment received and established only for subjects who survived at least 5 years following cancer diagnosis. The prospective cohort was established in 2005 by contacting adult subjects that were still alive. Subjects were sampled by directly administering a manual questionnaire at their home. The addresses of living subjects needed to be obtained prior to self-administered questionnaire follow-up. This was done by consulting the National Inter-Scheme Health Insurance Register (RNIAM). Access to RNIAM, which enables the FCCS to obtain the addresses of the individuals concerned through agencies serving National Health Insurance benefits, has been authorised by the Decree dated 04 March 2003, published on 14 March 2003 in the Official Journal of the French Republic. Access to RNIAM is justified by the direct interest of informing the patients of the possible risks in adulthood and appropriate medical monitoring procedures. All major FCCSS topics will be monitored individually by the SNIIR-AM (DCIR base), except for those that explicitly refused to participate.

Database objective

Main objective	The main objective of the study is to improve knowledge about the long-term health and social outcomes for children and adults cured of cancer. The FCCSS particularly focuses on: - Estimating the incidence of iatrogenic diseases occurring after long-term treatment of a childhood tumour; - Identifying and quantifying risk factors associated with these diseases in order to reduce iatrogenic risks and customise treatment;

	- Identifying clinical markers of the progression of these diseases in order to improve early diagnosis and treatment - Implementing customised follow-up consultations and the preventative actions required. This study was implemented in order to increase knowledge on the long-term social and health implications of cancer treatment received during childhood. The FCCSS follows the Euro2K study, which showed that survivors of childhood cancer are at a significantly high risk of serious iatrogenic events (e.g. long-term mortality, second cancer, diabetes, cardiac diseases, and cerebrovascular disease).
Inclusion criteria	Subjects under 21 years old diagnosed with cancer before 2000 in France.

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)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Initially, the project involved the following French paediatric oncology centres that combat cancer in Villejuif, Reims, Paris, Nice and Toulouse. The project also included 3 London hospitals with an English researcher (Mike Hawkins). 31 French paediatric oncology institutions that comprehensively register cancer patients have joined the project since 2012. The study is also based on clinical trials, existing cohorts and French cancer registries.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	1985

Size of the database

Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	- 4,500 (1942-1985) - Euro2K - 10,000 (2000) - 16,000 (2014).

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical; data from medical records from healthcare institutions/French cancer registries/therapeutic trials; medical data indirectly collected from healthcare professionals (examinations/consultations) and directly from individuals.
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Questionnaire is completed by subjects that includes information on occupation, social status, integration, family and professional networks, housing, access to bank loans, fertility, children, medical problems, access to healthcare, treatment, treatment plan and continuity between childhood and adulthood.
Paraclinical data (detail)	Dosimetry data and imaging data.
Biological data (detail)	In order to identify genetic variants that may modulate the iatrogenic risk of cancer treatments, a bank of biological samples (BioF study), nested in the FCCSS was formed. DNA samples are made from saliva samples collected with Oragene ® kit. A blood sample bank was also established.
Administrative data (detail)	An important phase of the study is to indirectly and/or indirectly collect identification data from the concerned individuals (domicile, gender, surname, first name, date and place of birth).
Presence of a biobank	No
Health parameters studied	Health event/morbidity

	Health event/mortality Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Other (detail)	Weight, height, children, reproductive health (hormone cycle, contraception, prevention, motherhood, child conception); alcohol consumption and smoking; disease follow-up care, cancer treatment, radiotherapy reconstitution and dosimetry.

Procedures

Data collection method	Survival follow-up is carried out for the entire cohort by researching vital status. The questionnaire follow-up is carried out for subjects that are still alive and who have a complete address. The self-administered questionnaire includes about 200 questions on social and professional integration, access to bank loans, health, quality of live, perceived health, family and social networks, as well as children.
Classifications used	International Classification of Diseases (ICD-O, ICD-9, ICD-10); DCI, INSEE municipality and country codes.
Participant monitoring	Yes
Details on monitoring of participants	Survival follow-up is carried for over 20 years (retrospective data); data collected by questionnaire are collected since 2005. The FCCSS cohort is subject to longitudinal follow-up for an indefinite duration.
Links to administrative sources	Yes
Linked administrative sources (detail)	Participant survival is ascertained by retrieving vital status (RNIPP - INSEE), medical causes of death (CépiDc - INSERM) and postal address (French postal service, RNIAM). A pairing with SNIIR-AM (PMSI data, ALD, AT-MP, healthcare consumption) is also performed.

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Publis-HAL-FCCSS-EURO2K
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-FCCSS-EURO2K
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	The use of anonymised data on the outcome of children cured of cancer from the top 5 cancer centers is possible for any research by a team with proven experience in the field of expertise. Usage is determined on a case-by-case and is governed by an agreement. The use of anonymised FCCSS data shall be possible for any external research team involvong the outcome of children cured of cancer and shall be determined on a case-by-case basis following submission of the project to the cohort scientific committee. Participants from paediatric oncology departments will have access to their patients' data.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only