EPOPA - Cohort of patients overexposed during a course of conformal radiotherapy for a prostate adenocarcinoma in Jean Monnet Hospital in Epinal

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General

Identification

Detailed name	Cohort of patients overexposed during a course of conformal radiotherapy for a prostate adenocarcinoma in Jean Monnet Hospital in Epinal
Sign or acronym	EPOPA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL

General Aspects

Medical area	Cancer research Nuclear medicine
Health determinants	Iatrogenic Occupation
Keywords	doses, irradiated tissues, overexposure, complications, iatrogenic effects, dosimetry

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	Programme hospitalier de recherche clinique

Governance of the database

Sponsor(s) or organisation(s) responsible	APHP
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.	Prospective Inclusion cut-off date: 01/12/2009

Database objective

Main objective	To correlate received doses and volume of irradiated normal tissues in the cohort of patients who underwent overexposure of varying degrees, as well as complications observed with biologic, phenotypic and genetic data. The incidence and severity of iatrogenic effects and sequelae of radiotherapy (according to soma-lent and CTCAE scales) are correlated using a precise reconstruction of actual irradiation dosimetry received by each patient (total radiation dose prescribed and issued by daily controls) according to technical dossier data and system treatment planning. Secondary objective: to gather biological collections from blood samples (serum bank, DNA bank, lymphocytes) to correlate iatrogenic complications and radiation doses to normal tissues with biologic, phenotypic and genetic data. These collections will be used to: - identify factors associated with susceptibility to radiation-induced complications in normal tissues; - study radiation fibrosis biology; - study normal tissue radiosensitivity: rectal wall; - study the biological control dose-response relationship for prostate adenocarcinoma; - implement radiogenic fibrosis treatment protocols.
Inclusion criteria	Patients treated for a prostate adenocarcinoma in the radiation department of the Jean Monnet Hospital between 2000 and 2006.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	Departmental
French regions covered by the database	Alsace Champagne-Ardenne Lorraine
Detail of the geography area	Epinal Hospital, Vosges department

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	09/2008

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	120 sujets inclus avec recueil sanguin / 120 with blood sample selection409 patients concernés, dont 29 sont décédés / 409 concerned with 29 deaths

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Face to face interview
Biological data (detail)	Blood samples
Presence of a biobank	Yes

Contents of biobank	Serum Plasma Fluids (saliva, urine, amniotic fluid, ?) Tissues DNA
Details of biobank content	Serum bank, plasma bank, DNA bank, lymph bank and tissue bank (for patients who have had a rectum amputation).
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation
Procedures	
Data collection method	Interviews: manual input from a paper questionnaire Clinical examinations: handwritten
Participant monitoring	Yes
Details on monitoring of participants	Duration: 5 years
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/HAL-EPOPA
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-EPOPA
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	To be decided if data may be used by academic teams. Data may not be used by industrial teams.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only