

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

Head :Simon Jean-Marc, SERVICE D'ONCOLOGIE RADIOTHÉRAPIQUE GROUPE HOSPITALIER PITIÉ-SALPÊTRIÈRE  
47-83 BOULEVARD DE L'HÔPITAL, 75651 PARIS CEDEX 13 AP-HP

Gourmelon Patrick, INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE (IRSN) DIRECTION DE LA  
RADIOPROTECTION DE L'HOMME IRSN

Tabassome Simon, UNITÉ DE RECHERCHE CLINIQUE DE L'EST PARISIEN SERVICE DE PHARMACOLOGIE  
FACULTÉ DE MÉDECINE PIERRE ET MARIE CURIE UNITÉ DE RECHERCHE CLINIQUE DE L'EST PARISIEN  
SERVICE DE PHARMACOLOGIE FACULTÉ DE MÉDECINE PIERRE ET MARIE CURIE

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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)

Name of the director Simon

Surname Jean-Marc

Address 75013 PARIS

Phone +33 (0)1 42 17 81 74

Email jean-marc.simon@psl.aphp.fr

Unit SERVICE D'ONCOLOGIE RADIOTHÉRAPIQUE  
GROUPE HOSPITALIER PITIÉ-SALPÊTRIÈRE 47-83  
BOULEVARD DE L'HÔPITAL, 75651 PARIS CEDEX 13  
AP-HP

Name of the director Gourmelon

Surname Patrick

Address 92262 FONTENAY-AUX-ROSES

Phone +33 (0)1 58 35 77 54

Email patrick.gourmelon@irsn.fr

Unit INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ  
NUCLÉAIRE (IRSN) DIRECTION DE LA  
RADIOPROTECTION DE L'HOMME IRSN

Name of the director Tabassome

Surname Simon

Address 75012 PARIS

Phone +33 (0)1 40 01 14 57

Email tabassome.simon@sat.aphp.fr

Unit UNITÉ DE RECHERCHE CLINIQUE DE L'EST  
PARISIEN SERVICE DE PHARMACOLOGIE FACULTÉ  
DE MÉDECINE PIERRE ET MARIE CURIE UNITÉ DE  
RECHERCHE CLINIQUE DE L'EST PARISIEN SERVICE  
DE PHARMACOLOGIE FACULTÉ DE MÉDECINE  
PIERRE ET MARIE CURIE

## 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more)     |
| Population covered                           | Sick population   |
| Gender                                       | Male<br>Woman   |
| Geography area                               | Departmental  |
| French regions covered by the database       | Alsace Champagne-Ardenne Lorraine   |
| Detail of the geography area                 | Epinal Hospital, Vosges department  |
| <b>Data collection</b>                       |   |
| <b>Dates</b>                                 |   |
| Date of first collection (YYYY or MM/YYYY)   | 09/2008   |
| <b>Size of the database</b>                  |   |
| 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 selection<br>409 patients concernés, dont 29 sont décédés / 409 concerned with 29 deaths |
| <b>Data</b>                                  |   |
| Database activity                            | Data collection completed   |
| Type of data collected                       | Clinical data<br>Declarative data<br>Biological data  |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration  |
| Declarative data (detail)                    | Face to face interview  |
| Biological data (detail)                     | Blood samples   |
| Presence of a biobank                        | Yes   |

|   |  |
|---|--|
| Contents of biobank   | Serum<br>Plasma<br>Fluids (saliva, urine, amniotic fluid, ?)<br>Tissues<br>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<br>Health event/mortality<br>Health care consumption and services                       |
| Care consumption (detail)   | Medical/paramedical consultation   |
| <b>Procedures</b>   |  |
| Data collection method  | Interviews: manual input from a paper questionnaire<br>Clinical examinations: handwritten                      |
| Participant monitoring  | Yes  |
| Details on monitoring of participants   | Duration: 5 years  |
| Links to administrative sources   | No   |
| <b>Promotion and access</b>   |  |
| <b>Promotion</b>  |  |
| Link to the document  | <a href="http://tinyurl.com/HAL-EPOPA">http://tinyurl.com/HAL-EPOPA</a>  |
| Description   | List of publications in HAL  |
| Link to the document  | <a href="http://tinyurl.com/Pubmed-EPOPA">http://tinyurl.com/Pubmed-EPOPA</a>                                  |
| Description   | List of publications in Pubmed   |
| <b>Access</b>   |  |
| 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  |