COBLAnCE - A COhort to study BLAdder CancEr

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General

Identification

Detailed name	A COhort to study BLAdder CancEr
Sign or acronym	COBLAnCE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°912260 525/10/2012°, CPP Ile-de-France VII : CO-12-001 (01/02/2012)

General Aspects

Medical area	Cancer research
Health determinants	Addictions Genetic Geography Healthcare system and access to health care services Lifestyle and behavior Medicine Nutrition Occupation Social and psychosocial factors
Keywords	Bladder cancer, urology, cancer research, cohort

Scientific investigator(s) (Contact)

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Organization	Inserm
Collaborations	
Funding	
Funding status	Public
Details	ANR "Investissements d'avenir -Grand emprunt"
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE - 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 carried out as part of an interventional study	No
Additional information regarding sample selection.	Cases at the participating hospitals will be identified as soon as possible after diagnosis. Early identification will be achieved through active searches, involving periodic visits to the hospital departments in which cases are diagnosed or treated. Inclusion period will last 2 years. The local coordinator will maintain a record of the cases identified and will indicate the reasons for which patients were not interviewed or material not collected (e.g., refusal, treatment).
Database objective	
Main objective	1) To test the association between constitutional DNA polymorphism, environmental parameters, molecular subtype and clinical data. The inclusion of features of both the tumour and the host will

	facilitate the discovery of tumourigenesis mechanisms, drugable targets and diagnostic and prognostic biomarkers. 2) To provide insight into the tumour progression knowledge and to help to identify biomarkers by the sequential sampling of recurrent tumors, plasma or urine from individual patients during follow_up. 3) To validate and extend our prior results regarding the molecular subtyping of bladder cancer on a large series of tumors collected prospectively. 4) To facilitate the transfer of study results into clinical practice thanks to the size and bladder cancer representativeness of the cohort. 5) To describe treatment patterns and to assess the direct and indirect costs of bladder cancer. The cost variability will be analyzed to identify the determinants of cost. This evaluation will pave the way for cost-benefit analyses of new biomarkers developed by the consortium. 6) To structure, at the national level, an interdisciplinary bladder cancer network including epidempiologists, bioinformaticians, health economists, molecular biologists, occupational physicians, pathologists and urologists, for coordinated and synergistic research actions and to make a significant contribution to a European multinational cohort and support international studies in genomics, in particular.
Inclusion criteria	Inclusion as soon as possible after diagnosis of bladder cancer in the 17 participating hospitals
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	National
Detail of the geography area	Metropolitan France
Data collection	
Dates	

Date of first collection (YYYY or MM/YYYY)	09/2012
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2000 patients
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	DISEASE MANAGEMENT > Disease presentation: presence of symptoms (hematuria, pollakuria, dysuria, urgency, hydronephrosis), alteration of health status > Procedures before diagnostic resection: urinary cytology, urine culture, abdominal ultrasound, urinary tract fibroscopies, imaging (scanner, MRI) > Diagnosis through transurethral resection of the bladder: Hervix or Narrow-Band-Imaging fluorescence, number and location of resected tumors, size and aspect of the largest tumor > Treatment: for NMIBC: intravesical instillations and cystectomy; for MIBC: chemotherapy, radiotherapy, for both NMIBC and MIBC: lymphadenectomy, urethrectomy, nephro-urethrectomy, urinary diversion, blood transfusion, any hospitalization and complications > Outcomes: locoregional and distant recurrences (dates, sites, pathology, treatments, etc.) and death (date and place). PATHOLOGY > Histological type and subtype, prognostic factors, pathological review for all cases at initial diagnosis and in case of recurrence. quality of life > Generic measures (EuroQol EQ-5D-3L & EORTC QLQ-C30) > Specific measures (EORTC-BLS24 & EORTC-BLM30)
Declarative data (detail)	Face to face interview
Details of collected declarative data	EPIDEMIOLOGIE : - Sociodemographic characteristics: age, gender, place of birth, educational level, marital status, household income, working situation, history of residences and of occupations - Lifestyle: history of tobacco

	consumption, dietary habits and physical activity > Medical history and medication use: weight, height, urinary tract infection, hematuria, kidney stones, skin or respiratory allergies, anti-hypercholesteremic and anti-inflammatory drugs, hormonal treatment, personal and family history of cancer.
Biological data (detail)	DNA, RNA, plasma, protein extracts from blood, tumors and/or urine
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) Tissues
Details of biobank content	Lymphocytes, plasma and red blood cells.Tumour tissues at first transurethral resection enbedding in paraffin. If the tumour is sufficiently large, a sample will be snap-frozen and stored at -80°.
Health parameters studied	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)	LQ (Lifestyle questionnaire) : demographic details (age/sex/education/ place of residence/ social class), complete smoking history, history of drinking habits (water, coffee, tea, alcohol, etc), occupational history and physiqcal activity, and personal medical history and familial history of cancer. ---- Economic questionnaire : all medical resources related to bladder cancer and their cost for each patient.
Procedures	
Data collection method	Clinical data on the tumour present on inclusion will be obtained from the review of clinical charts by trained monitors. The clinical and pathologic data will include all EAU factors used to predict recurrence and progression (tumour size, multiplicity, stage, grade, associated CIS). All patients will undergo identical interviews, during which they will complete a lifestyle questionnaire (LQ) and quality of life

	questionnaire (QOL). The lifestyle questionnaire is structured and will be used to collect the following information: demographic details (age/sex/education/place of residence/social class), complete smoking history, history of drinking habits (water, coffee, tea, alcohol, etc), occupational history and physical activity, and personal medical history and familial history of cancer.Health care resources use and quality of life data will be collected for each patient at baseline and every year during follow-up. Healthcare resource use will be collected both from the medical records in the participating centres and interviewing the patients by telephone. Each patient should give its consent to this data collection including access to national health insurance claims data. The economic questionnaire will be structured according the course of the disease (diagnosis, initial treatment, follow-up, recurrences, and progression including metastatic disease). All medical resources (inpatient - surgery, chemotherapy, etc?- , and, outpatient services and visits) related to bladder cancer will be collected for each patient and during the whole study period. Sick leaves will be collected on a yearly basis until the end of follow-up (e.g. 6 years after inclusion). Unit cost information will be gathered from official sources (mainly national health insurance) to cost each type of resources and compute direct and indirect costs. A special attention will be paid to innovative drugs and technologies including biomarkers research. All this information will be collected on specific structured logsheets.
Participant monitoring	Yes
Details on monitoring of participants	6 years
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Terms are currently being defined

Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only