CONNEXION CANCER - Risk score for venous thromboembolism

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General

Identification

Detailed name	Risk score for venous thromboembolism
Sign or acronym	CONNEXION CANCER
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : AR 104238

General Aspects

Medical area	Cancer research Cardiology
Health determinants	Iatrogenic Medicine
Keywords	prospective cohort, risk score, oncology

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	Laboratoire GSK

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private

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 is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	The investigating doctors will propose the study to patients that meet the inclusion criteria during a normal visit in the department. - Cohort of patients with a specific blood sample Doctors will present the objectives of the study and will explain the constraints linked to it (taking of an additional blood sample). The doctors will have patients who accept to participate in the study sign the consent agreement and will complete a prescription to request additional biological examinations for carrying out the dosage for the Tissue Factor, Thrombin Generation Time, Soluble P-selectin, D-dimers, Factor VIII and Fibrinogen which are not carried out in common medical practice. - Cohort of patients without a specific blood sample Doctors will present the objectives of the study and will give a specific information note to the patients. The protocol for the study does not require any visit or examination other than those performed in common practice.

Database objective

Main objective	Develop a risk score of the appearance of venous thrombosis in patients with cancer, using clinical and biological parameters

Inclusion criteria	? Patient aged 18 years or older ? Patient having: - Either metastatic cancer, regardless of its location (except for hematopoietic cancers), - Or one of the following cancers, at all stages of development: stomach, ovary, pancreas, lung, bladder, testicle ? Patient: - For whom the cancer is currently being treated or - For whom the cancer treatment is scheduled or - Who do not have any cancer treatment in progress but who gave received a treatment (in the last 3 years) via chemotherapy or radiotherapy or hormone therapy or targeted therapies ? In order to be included in the study, the subject for whom a search of additional biological parameters will be carried out must: - having given their free and informed consent in writing, - accept an additional blood sample be taken on the day of inclusion.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2011
Size of the database	

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2500

Data

Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Biological data (detail)	? CBC (hemoglobin, platelets and white blood cells)? CRP? Plasma creatinine? Tissue Factor? Thrombin Generation Time? Soluble P-selectin? D-dimers? Factor VIII? Fibrinogen
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	A Clinical Study Technician (CST) will complete the observation logbook using the data collected in the medical dossier and will add the values of the biological parameters specifically dosed for the study using the results sent by the central laboratory.
Participant monitoring	Yes
Details on monitoring of participants	At 6 months: During a normally-scheduled follow-up visit 6 months after inclusion [tolerance of -7 days ; +21 days]. The doctor will validate with the patient if there was a venous thromboembolic event since inclusion. If such is the case, the doctor will note in the patient's medical dossier all of the elements making it possible to medically qualify the thromboembolic event, the date of occurrence and the treatments undertaken. The follow-up observation logbook will then be completed by the CST.

Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only