SIGNAL - Cohort of Breast Cancer Patients. Identification of Genetic Determinants that Influence Resistance/Sensitivity and/or Toxicity to Adjuvant Cancer Treatment and Genetic Determinants for Developing Breast Cancer.

Head :Pauporté Iris
Pivot Xavier
Cox David
Deleuze Jean-François
Blanché-Koch Hélène

Last update : 06/20/2016 | Version : 1 | ID : 73302

General

Identification

Detailed name	Cohort of Breast Cancer Patients. Identification of Genetic Determinants that Influence Resistance/Sensitivity and/or Toxicity to Adjuvant Cancer Treatment and Genetic Determinants for Developing Breast Cancer.
Sign or acronym	SIGNAL
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCP 28/01/2009; ANSM: B881131-60

General Aspects

Medical area	Cancer research
Pathology (details)	Breast cancer
Health determinants	Genetic Healthcare system and access to health care services Iatrogenic Medicine
Keywords	genetic determinant, breast, cancer, treatment

Scientific investigator(s) (Contact)

Name of the director	Pauporté
Surname	Iris

Address	INSTITUT NATIONAL DU CANCER 52 AVENUE MORIZET 92513 BOULOGNE-BILLANCOURT
Phone	+33 (0)1.41.10.14.86
Email	ipauporte@institutcancer.fr
Organization	National Cancer Institute
Name of the director	Pivot
Surname	Xavier
Phone	+33 (0)3 81 66 93 86
Email	Xavier.pivot@univ-fcomte.fr
Organization	Besançon University Hospital
Name of the director	Cox
Surname	David
Phone	+33 (0)4 78 78 59 12
Email	david.cox@inserm.fr
Organization	Lyon Cancer Research Centre
Name of the director	Deleuze
Surname	Jean-François
Email	deleuze@cng.fr
Organization	Fondation Jean Dausset-CEPH & National Genotyping Centre
Name of the director	Blanché-Koch
Surname	Hélène
Phone	+33 (0)1 53 72 50 42
Email	blanche@cephb.fr
Organization	Fondation Jean Dausset-CEPH

Collaborations

Participation in projects,	Yes

networks and consortia

Details	ICGC (International Consortium of Genomics of Cancer)

Funding

Funding status	Public
Details	National Cancer Institute

Governance of the database

Sponsor(s) or organisation(s) responsible	Institut National du Cancer
Organisation status	Public
Presence of scientific or steering committees	Yes

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	Yes
Details	Performed at individual level
Additional information regarding sample selection.	Enrolment in healthcare facilities authorised to carry out cancer research. The physicians in charge of patient enrolment in the SIGNAL clinical trial offer breast cancer patients with overexpression or non-overexpression of the HER2 receptor the opportunity to participate in this genetic study. 3 groups are formed: Group HER2+: The HER2+ group will be made up of breast cancer patients with HER2 receptor

	overexpression, treated with Trastuzumab and who agreed to participate in the study. Patients treated with Trastuzumab as part of a clinical trial (e.g. PHARE) are eligible for the SIGNAL trial. Group HER2-: The HER2- group will be made up of breast cancer patients with non-overexpression of the HER2 receptor who agreed to participate in the study. Healthy Control subjects: Recruited from other cohorts.
Database objective	
Main objective	The aims of this study are: ? to identify determinants that influence resistance or sensitivity following adjuvant treatment with Herceptin®; ? to identify determinants of cardiac toxicity following adjuvant treatment with Herceptin®; ? to identify genetic determinants for developing different types of breast cancer: HER2+, triple negative, RH+; ? to identify genetic determinants for developing breast cancer.
Inclusion criteria	1. Women over 18 years old. 2. Histologically confirmed, non-metastatic, operable breast adenocarcinoma. 3. HER2+ tumour: all patients undergoing adjuvant treatment with Trastuzumab. 4. Signed informed consent.
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	Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or	2009

MM/YYYY)	
Date of last collection (YYYY or MM/YYYY)	2017
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	9,600
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Type of treatment received; breast cancer subtype; clinical events (relapse, death); heart monitoring.
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Physical attributes; reproductive history; family history; personal medical history; family records; physical activity; exposure to tobacco and alcohol; exposure to radiation.
Paraclinical data (detail)	Mammography; CA15-3 (optional)
Biological data (detail)	Blood; tumour sample
Presence of a biobank	Yes
Contents of biobank	Whole blood Plasma Tissues Cell lines DNA
Details of biobank content	DNA; plasma
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services

Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	By participating physicians and study investigators
Quality procedure(s) used	Implemented by independent operators
Participant monitoring	Yes
Monitoring procedures	Monitoring by convocation of the participant
Details on monitoring of participants	Patients will be monitored for 5 years by: ? clinical examination every 6 months ? CA15-3 every 6 months (optional) ? annual mammogram
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)	Fully anonymised clinical data (no initials or order number; returned to correlation table; no date of birth; no reference to the healthcare centre or investigator that enrolled the patient) may be made readily available to third parties; please contact those in charge of the study. Requesting parties undertake to reference the study and its sponsor in all publications resulting from these data.
Access to aggregated data	Free access
Access to individual data	Free access