BREAST CANCER CHEMOTHERAPY - Prospective Cohort of Patients Receiving Neoadjuvant Chemotherapy for Breast Cancer

Head :Ghiringelli François, INSERM CRI 866 EPIDEMIOLOGIE CANCER ET NUTRITION FACULTE DE MEDECINE
Coudert , ONCOLOGIE MEDICALE

Last update : 08/04/2014 | Version : 1 | ID : 60092

General

Identification

Detailed name	Prospective Cohort of Patients Receiving Neoadjuvant Chemotherapy for Breast Cancer
Sign or acronym	BREAST CANCER CHEMOTHERAPY
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Date de réception de l'avis favorable de la CNIL : 05/02/2002

General Aspects

Medical area	Cancer research
Others (details)	Breast cancer
Keywords	state, local recurrence, metastatic, histological data, imaging, Health episodes, death, treatment, classification, surgery

Scientific investigator(s) (Contact)

Name of the director	Ghiringelli
Surname	François
Email	fghiringhelli@dijon.fnclcc.fr
Unit	INSERM CRI 866 EPIDEMIOLOGIE CANCER ET NUTRITION FACULTE DE MEDECINE
Organization	CHU
Name of the director	Coudert
Address	21079 DIJON

Email	bcoudert@dijon.fnclcc.fr
Unit	ONCOLOGIE MEDICALE
Organization	CENTRE GEORGES FRANÇOIS

Collaborations

Funding

Funding status	Public
Details	CENTRE GEORGES FRANCOIS LECLERC

Governance of the database

Sponsor(s) or organisation(s) responsible	SERIVCE D'ONCOLOGIE ET UNITE DE BIOSTATISTIQUE, CHU DIJON
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.	Inclusion method: Prospective

Database objective

Main objective	General objective: To evaluate the medical, clinical, biological and therapeutic characteristics of breast cancer patients receiving neoadjuvant chemotherapy Secondary objectives: - To evaluate the long-term impact of therapeutic schemas on recurrence-free overall survival; - To validate the current prognostic scores from a U.S. population on an independent French cohort; - To identify prognostic variables and select those relevant to

	the establishment and evaluation of a new score from our database to reflect new biological data (Chevallier and Sataloff scores and molecular classification); - To compare the prognostic qualities of the new score to the U.S. score; - To conduct an external validation of these scores (through collaboration with the Institut Gustave Roussy team in Villejuif and the Institute Bergonie team in Bordeaux); - To isolate genetic (constitutional), genomic (tumour) or immunohistological factors with predictive power for treatment response and prognosis.
Inclusion criteria	- Patients with breast cancer receiving neoadjuvant chemotherapy; - patient's written consent.
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	Woman
Geography area	Regional
French regions covered by the database	Bourgogne Franche-Comté
Detail of the geography area	Burgundy
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/1990
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	465
Data	
Database activity	Data collection completed

Type of data collected	Paraclinical data Biological data
Paraclinical data (detail)	Imaging
Biological data (detail)	Type of samples taken: Initial biopsy and surgical specimen (frozen or paraffin conservation) serum
Presence of a biobank	Yes
Contents of biobank	Serum DNA
Details of biobank content	Serum bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Clinical examinations: Direct input Biological analysis: Direct input
Participant monitoring	Yes
Details on monitoring of participants	(Indeterminate duration)
Links to administrative sources	Yes
Linked administrative sources (detail)	PMSI, Pathology registry
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/21750556
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/21437909
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/20229175
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/18413832
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams Access for biological portion of study carried out in INSERM Unit U866 (Prof. Eric Solary, Dr. Ghiringhelli) in Dijon and INSERM Unit 645 in Besançon 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