

CANTO - Chronic toxicities in patients with early breast cancer

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General

Identification

Detailed name Chronic toxicities in patients with early breast cancer

Sign or acronym CANTO

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation N° CPP : 11.039 N° AFSSAPS : B111158-20

General Aspects

Medical area Cancer research

Health determinants Genetic
Iatrogenic

Others (details) breast cancer

Keywords adversed effects, long term toxicity, financial impact, predictors for chronic toxicity, toxicity, psychological impact, social impact, biomarkers

Scientific investigator(s) (Contact)

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Unit Inserm U981

Organization Institut Gustave Roussy

Collaborations

Funding

Funding status	Mixed
Details	ANR "Investissements d'avenir -Grand emprunt", Biomérieux, INCA,
Governance of the database	
Sponsor(s) or organisation(s) responsible	Institut Gustave Roussy (IGR)
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Fédération Nationale des centres de lutte contre le Cancer
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 is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	<p>The primary goal will be to generate predictors of chronic toxicity in patients with early breast cancer treated with anticancer agents.</p> <p>This project will include four specific aims:</p> <ul style="list-style-type: none"> - To develop a database of chronic toxicity in a cohort of 20 000 women with stage I-III breast cancer - To describe incidence, clinical presentation, biological characteristics and outcome of chronic toxicities - To describe the psychosocial and economic impact of chronic toxicities - To generates predictors for chronic toxicities

Inclusion criteria	Women with non-metastatic breast cancer (I to III stade) treated in one of the 10 medical centers involved in the study
Population type	
Age	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 territory
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	20 000
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Paraclinical data (detail)	Heart US, MRI joint, electromyogram, bone densitometry, Uterine US
Presence of a biobank	Yes
Contents of biobank	Whole blood

Details of biobank content	whole blood
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	Inclusion: each women will fill a first questionnaire for demographics and living conditions, and a set of validated questionnaires related to QoL (BR 23) and special psychological dimensions. MDs will fill the questionnaire
Participant monitoring	Yes
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Ask the person in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only