

CANTO - Chronic toxicities in patients with early breast cancer

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Last update : 01/18/2013 | Version : 1 | ID : 3082

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 |

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|---|--|
| 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 |