KADOR - A French retrospective study describing the epidemiology and the therapeutic management of patients treated by Herceptin® based neoadjuvant treatment for HER2-positive early breast cancer.

Head :Roche Medical Data Center

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General

Identification

Detailed name	A French retrospective study describing the epidemiology and the therapeutic management of patients treated by Herceptin® based neoadjuvant treatment for HER2-positive early breast cancer.
Sign or acronym	KADOR
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML41346

General Aspects

Medical area	Cancer research
Study in connection with Covid-19	No
Pathology (details)	Early HER2+ Breast cancer
Health determinants	Medicine
Keywords	KADOR

Scientific investigator(s) (Contact)

Name of the director	Roche Medical Data Center
Address	4 cours de l'Ile Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private

Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes

Additional contact

Name of the contact	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html

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	Primary objective: To describe therapeutic management of HER2-positive early breast cancer adults' patients who have received an adjuvant treatment following Herceptin® based neoadjuvant therapy and breast surgery. Secondary objectives: The 2 key secondary objectives are: 1. To describe the clinical characteristics of the

	patients included in the cohort, overall and per pathological response status; 2. To measure the invasive disease-free survival (IDFS) and overall survival (OS), according to pathologic response status. Other objectives: 3. To characterize adjuvant treatment failure outcomes including death, disease progression, and relapses; 4. To describe health care resources utilization by the targeted patients; 5. To estimate the number of HER2-positive early breast cancer patients who underwent breast surgery following Herceptin® based neoadjuvant treatment in France over a year (through the constitution of a registry of these patients) and number of HER2 positive early breast cancer patients with non pCR.
Inclusion criteria	Inclusion criteria: - A confirmed diagnosis of HER2-positive early breast cancer; - Initiated Herceptin® based neoadjuvant treatment during 2014 (inclusion period) followed by a breast surgery; - A visit to any of the oncologist participating in the study during the 1-year inclusion period. Exclusion criteria: -Patients with bilateral breast cancer, or participating in a clinical trial for neoadjuvant or adjuvant treatment, or already included in the registry of another participating site of the study, or who expressed disagreement on the use of their medical data will be excluded from the site's registry.
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
Pathology	D05 - Carcinoma in situ of breast
Gender	Woman
Geography area	National

Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2018
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	301
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Neoadjuvant treatment strategy and non-drugs treatments (surgery and radiotherapy) - Adjuvant treatment strategy and modification - Inclusion criteria variables, demographic, anthropometric, clinical and cancer characteristics - Weight, comorbidities of interest at the time of adjuvant treatment initiation - Date of last visit of the patient during the follow-up period, disease progression and reason for earlier end of observation or follow-up - Health care resources utilizations - Start and end date of patient inclusion in the registry - Date of inclusion of the first patient included and the last patient included in the registry - Number of consultations at the site during the inclusion year - Adjuvant treatment with trastuzumab (yes/No) - Type of surgery and pathologic response status.
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	eCRF

Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only