

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

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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 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