LORHA - A Retrospective Study to Characterize Patients With HER2-positive Metastatic or Locally Advanced Breast Cancer, Treated by Herceptin® as 1st Line-therapy and Without Progression for at Least 3 Years Followed by a 1-year Prospective Study for Patients Still Alive

Head :Roche Medical Data Center

Last update : 08/23/2022 | Version : 1 | ID : 74136

General

Identification

Detailed name	A Retrospective Study to Characterize Patients With HER2-positive Metastatic or Locally Advanced Breast Cancer, Treated by Herceptin® as 1st Line-therapy and Without Progression for at Least 3 Years Followed by a 1-year Prospective Study for Patients Still Alive
Sign or acronym	LORHA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML23001

General Aspects

Medical area	Cancer research
Study in connection with Covid-19	No
Pathology (details)	HER2-positive Metastatic or Locally Advanced Breast Cancer
Health determinants	Iatrogenic Medicine
Keywords	Herceptin

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: This observational study will characterize retrospectively patients with HER2-positive metastatic or locally advanced breast

	cancer who had received treatment with Herceptin (trastuzumab) in 1st line and who were without progression for at least three years. Secondary objectives: The secondary objectives of this study were to describe: - The progression-free survival, time to progression and patients overall survival; - Modalities of use of trastuzumab, the duration of treatment and the reasons leading to treatment discontinuation; - Antineoplastic treatments in combination with trastuzumab and after discontinuation of trastuzumab treatment; - Relevant biological tumor markers; - The safety of trastuzumab treatment.
Inclusion criteria	Inclusion criteria: - Woman >= 18 years; - With HER2-positive metastatic breast cancer or locally-advanced breast cancer; - Treated with trastuzumab as first-line therapy; - Without progression for at least 3 years after initiation of trastuzumab treatment; - Alive or not alive, and treated or not treated with trastuzumab at the time of inclusion; For patients alive at the time of inclusion: - Having been informed orally and in writing about the study and having given their written consent to the automatic processing of her personal data and their consultation by a duly authorized third party; - For the patients who accepted the centralized histological analysis of their primitive tumor, a written consent. Exclusion criteria: - Disease progression <3 years after beginning 1st-line therapy with Herceptin.
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)	2011
Date of last collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	160
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	evaluation/inclusion criteria - initial breast cancer diagnosis - neo-adjuvant treatments - adjuvant treatments - entry in metastatic or locally advanced disease - adverse events since Herceptin® initiation - Progression - Evaluation at M6 and M12 - chemotherapy in 1st, 2nd and 3rd lines - hormonotherapy in 1st, 2nd and 3rd lines - Progression after 1 and 2nd lines - treatment by Herceptin® in neo-adjuvant/adjuvant - treatment by Herceptin® in metastatic
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality 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