

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

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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 LORHA

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: 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 \geq 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